DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

Agenda

ICD-10 Coordination and Maintenance Committee Meeting
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Virtual Meeting
ICD-10-PCS Topics
September 10, 2024

Zoom Webinar and Dial-In Information

- This meeting will be conducted via Zoom Webinar. The URL to register to join the Zoom Webinar, the password, and the call-in numbers are the same for both days of the meeting. Meeting details for each day are as follows.
- Day 1: September 10, 2024: The meeting will begin promptly at 9:00 AM ET and will end at 5:00 PM ET. Lunch will be held from 12:30 PM to 1:30 PM.
- Day 2: September 11, 2024: The meeting will begin promptly at 9:00 AM ET and will end at 5:00 PM ET. Lunch will be held from 12:30 PM to 1:30 PM.

To minimize feedback to the maximum extent possible, join the meeting using only **ONE** of the options listed below.

Option 1: Remote participants (attendees wishing to both view slides and ask questions during the Q&A portions of the meeting) must register to join the Zoom Webinar via the web. To register to join this Zoom Webinar conference from a PC, MAC, iPad, iPhone or Android device as well as, connect to the audio portion of the conference:

Register in advance for this webinar:
https://cms.zoomgov.com/webinar/register/WN_8hiZrGNcQYCFuH9P7LCloQ
Webinar ID: 160 744 0104
Passcode: 621302

Option 2: Dial-in access is available for listen-only participants. Listen-only participants are participants who wish to only listen to the meeting and do not wish to comment or ask questions during the Q&A portions of the meeting.

1. From your phone, dial U.S.*: 669-254-5252 or 646-828-7666 or 833-568-8864 (Toll Free)
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*If dialing in from outside of the U.S., visit https://cms.zoomgov.com/u/abB771Tkmo for a list of Zoom International Dial-in Numbers.

Option 3: To join this Zoom Webinar conference from an H.323/SIP room system:

1. From your room system, dial 161.199.138.10 (US West) or 161.199.136.10 (US East)
2. Enter the webinar ID: 160 744 0104
   Passcode: 621302

SIP: 1607440104@sip.zoomgov.com
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Those participating in the Zoom Webinar may ask questions during the Q&A portions of the meeting using the "Raise Hand" feature. If time does not permit you to comment or ask a question during the Q&A session, you may submit comments and questions at any time using the "Q&A" feature. All comments and questions submitted using the "Q&A" feature, along with CMS' responses to them, will be posted as soon as possible after the meeting in the "Downloads" section of the CMS web page located at: https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials. Remaining questions may be submitted via the CMS ICD-10 Procedure Code Request mailbox at ICDProcedureCodeRequest@cms.hhs.gov.

Note: Proposals for diagnosis code topics will be led by the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) and are scheduled to begin following completion of the CMS procedure code proposals on September 10, 2024. Remaining diagnosis code topics will continue to be presented on September 11, 2024. Please visit CDC's website for the Diagnosis agenda located at the following address: https://www.cdc.gov/nchs/icd/icd-10-maintenance/meetings.html.

If you require reasonable accommodation with an interpreter, please contact Mady Hue at marilu.hue@cms.hhs.gov or Andrea Hazeley at andrea.hazeley@cms.hhs.gov at least 72 hours prior to the event.

For questions about the registration process, please contact Mady Hue at marilu.hue@cms.hhs.gov or Andrea Hazeley at andrea.hazeley@cms.hhs.gov.

Instructions for Joining the ICD-10 Coordination and Maintenance Committee Meetings Govdelivery Subscriber List

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5. Check privacy box confirming your consent to our data privacy. Additional information on our data privacy policy can be found at www.cms.gov/privacy.
6. You should receive a SUCCESS message that states (your email address) has been successfully subscribed to ICD-10 Coordination and Maintenance
7. Click on the Finish button at bottom of screen.
8. You should now be on the Welcome Quick subscribe page. You can subscribe to receive information from a list of topics of your choice from our partner organizations by checking the boxes; unsubscribe by unchecking the boxes.
9. Scroll down to the bottom of the page. Check the data privacy policy box and click on Submit. Additional information on our data privacy policy can be found at www.cms.gov/privacy.
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Topics Being Considered for ICD-10-PCS Procedure Codes

Introductions & Overview 9:00 AM – 9:10 AM	Mady Hue, CMS Co-Chair, ICD-10 Coordination and Maintenance Committee
ICD-10-PCS Topics:	
1. Transcatheter Bypass of Left Atrium to Right Atrium via Coronary Sinus* Pages 14-16 9:10 AM – 9:25 AM	Mady Hue, CMS William Gray, MD Professor of Medicine, Sidney Kimmel School of Medicine Thomas Jefferson University
2. Administration of Roctavian™ (valoctocogene roxaparvovec-rvox) Pages 17-19 9:25 AM – 9:40 AM	Mady Hue, CMS Patrick Fogarty Executive Medical Director, U.S. Medical Lead, Hemophilia, GMAF BioMarin
3. Temporary Transvenous Diaphragm Activation*** Pages 20-23 9:40 AM – 9:55 AM	Jeanine DuVerney, CMS Nawzer Mehta, Ph.D. Senior Vice President of Clinical Affairs Lungpacer Medical Inc.
4. Insertion of Endovascular Anchors Pages 24-26 9:55 AM – 10:10 AM	Mady Hue, CMS Ross Milner, MD Professor of Surgery and Chief, Section of Vascular Surgery and Endovascular Therapy University of Chicago
5. External Fixation with Automated Strut Adjustment* Pages 27-32 10:10 AM – 10:25 AM	Mady Hue, CMS John Spence Reid, MD Professor and Vice Chair for Education, Department of Orthopaedics and Rehabilitation Chief, Division of Trauma Penn State Health/Penn State College of Medicine
6. Extracorporeal Interstitial Fluid Removal** Pages 33-35 10:25 AM – 10:40 AM	Jeanine DuVerney, CMS Daniel Bensimhon, MD Medical Director Advanced Heart Failure & Mechanical Circulatory Support Program

7. Intraoperative Donor Organ Protection in Renal Transplantation Pages 36-38 10:40 AM – 10:55 AM	Jeanine DuVerney, CMS Jeremy Kwarcinski CEO iiShield
8. Insertion of Heterotopic Bicaval Valves into Right Atrium Pages 39-42 10:55 AM – 11:10 AM	Mady Hue, CMS
9. Section X Updates Pages 43-49 11:10 AM – 11:20 AM	Jeanine DuVerney, CMS
10. Addenda and Key Updates* Pages 50-61 11:20 AM – 11:35 AM	Andrea Hazeley, CMS
11. Notice Regarding Upcoming Releases of the MS-DRG Grouper and Medicare Code Editor (MCE) Page 62 11:35 AM	Mady Hue, CMS
Closing Remarks	Mady Hue, CMS

Therapeutic Agent Topics Also Under Consideration for ICD-10-PCS Codes[1]

12. Administration of emapalumab-lzsg** Pages 63-65	Jeanine DuVerney, CMS
13. Administration of tarlatamab-dlle** Pages 66-68	Jeanine DuVerney, CMS

* *Request is for an April 1, 2025 implementation date.*

** *Request is for an April 1, 2025 implementation date and the requestor intends to submit an NTAP application for FY 2026 consideration.*

*** *Requestor intends to submit an NTAP application for FY 2026 consideration.*

[1] *NTAP-related ICD-10-PCS procedure code requests that involve the administration of a therapeutic agent will not be presented at the virtual meeting. The slide presentations for these procedure code topics are available at:* https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials.

Continuing Education Credits:
Continuing education credits may be awarded by the American Academy of Professional Coders (AAPC) or the American Health Information Management Association (AHIMA) for participation in CMS ICD-10 Coordination and Maintenance (C&M) Committee Meeting Conference Calls, Meetings and Webcasts.

Continuing Education Information for American Academy of Professional Coders (AAPC)
If you have attended or are planning to attend a CMS ICD-10 Coordination and Maintenance (C&M) Committee Meeting Conference Call, you should be aware that CMS does not provide certificates of attendance for these calls. Instead, the AAPC will accept your e-mailed confirmation and call description as proof of participation. Please retain a copy of your e-mailed confirmation for these calls as the AAPC will request them for any conference call you entered into your CEU Tracker if you are chosen for CEU verification. Members are awarded one (1) CEU per hour of participation.

Continuing Education Information for American Health Information Management Association (AHIMA)
AHIMA credential-holders may claim 1 CEU per 60 minutes of attendance at an educational program. Maintain documentation about the program for verification purposes in the event of an audit. A program does not need to be pre-approved by AHIMA, nor does a CEU certificate need to be provided, in order to claim AHIMA CEU credit. For detailed information about AHIMA's CEU requirements, see the Recertification Guide on AHIMA's web site.

Please note: The statements above are standard language provided to CMS by the AAPC and the AHIMA. If you have any questions concerning either statement, please contact the respective organization, not CMS.

Contact Information
Comments on the procedure code proposals presented at the ICD-10 Coordination and Maintenance Committee meeting should be sent to the following email address: ICDProcedureCodeRequest@cms.hhs.gov

Mady Hue
Marilu.Hue@cms.hhs.gov

Andrea Hazeley
Andrea.Hazeley@cms.hhs.gov

Jeanine DuVerney
Jeanine.DuVerney@cms.hhs.gov

ICD-10 TIMELINE

A timeline of important dates in the ICD-10 process is described below:

September 10-11, 2024	The September 2024 ICD-10 Coordination and Maintenance Committee Meeting will be held virtually by Zoom Webinar.
September 2024	Recordings and slide presentations of the September 10-11, 2024 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the following web pages: **Diagnosis code portion of the recording and related materials–** https://www.cdc.gov/nchs/icd/icd-10-maintenance/meetings.html **Procedure code portion of the recording and related materials–** https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials
October 1, 2024	New and revised ICD-10-CM and ICD-10-PCS codes go into effect along with MS-DRG changes. Final addenda available on web pages as follows: **Diagnosis addendum –** https://www.cdc.gov/nchs/icd/icd-10-cm/files.html **Procedure addendum –** https://www.cms.gov/medicare/coding-billing/icd-10-codes
October 11, 2024	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the September 10-11, 2024 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on April 1, 2025.**
November 2024	Any new ICD-10 codes that will be implemented on the following April 1 will be announced. Information on any new codes to be implemented April 1, 2025 will be posted on the following websites: https://www.cdc.gov/nchs/icd/icd-10-cm/files.html https://www.cms.gov/medicare/coding-billing/icd-10-codes/latest-news
November 15, 2024	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the September 10-11, 2024 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on October 1, 2025.**

December 6, 2024	**Deadline for requestors: Those members of the public requesting that topics be discussed at the March 18-19, 2025 ICD-10 Coordination and Maintenance Committee Meeting must have their requests submitted to CMS for procedures and to NCHS for diagnoses by this date.** **Procedure code requests should be directed to CMS at:** https://mearis.cms.gov. **Diagnosis code requests should be directed to NCHS at:** nchsicd10cm@cdc.gov. Requestors should indicate if they are submitting their code request for consideration for an October 1, 2025 implementation date, or an April 1, 2026 implementation date. The ICD-10 Coordination and Maintenance Committee will make efforts to accommodate the requested implementation date for each request submitted, however, the Committee will determine which requests will be presented for consideration for an October 1, 2025 implementation date or an April 1, 2026 implementation date.
January 2025	Federal Register notice for the March 18-19, 2025 ICD-10 Coordination and Maintenance Committee Meeting will be published. This will include the tentative agenda.
February 2025	Tentative agenda for the Procedure portion of the March 18, 2025 ICD-10 Coordination and Maintenance Committee Meeting posted on CMS webpage at: https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html Tentative agenda for the Diagnosis portion of the March 19, 2025 ICD-10 Coordination and Maintenance Committee Meeting posted on NCHS homepage at: https://www.cdc.gov/nchs/icd/icd-10-maintenance/meetings.html
February 1, 2025	ICD-10 MS-DRG Grouper software and related materials posted on CMS webpage at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software
February 1, 2025	Any updates to the ICD-10-CM and ICD-10-PCS Coding Guidelines will be posted on the following websites: https://www.cdc.gov/nchs/icd/icd-10-cm/files.html https://www.cms.gov/medicare/coding-billing/icd-10-codes

February 1, 2025	All ICD-10-CM and ICD-10-PCS code update files (includes April 1 update and full files from prior October 1) will be posted on the following websites: https://www.cdc.gov/nchs/icd/icd-10-cm/files.html https://www.cms.gov/medicare/coding-billing/icd-10-codes
March 18-19, 2025	The ICD-10 Coordination and Maintenance Committee Meeting is anticipated to be fully virtual by zoom and dial-in. Those who wish to attend must participate via Zoom Webinar or by dialing in.
March 2025	Recordings and slide presentations of the March 18-19, 2025 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the following web pages: **Diagnosis code portion of the recording and related materials–** https://www.cdc.gov/nchs/icd/icd-10-maintenance/meetings.html **Procedure code portion of the recording and related materials–** https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html
April 1, 2025	Any new or revised ICD-10 codes will be implemented on April 1, 2025.
April 18, 2025	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the March 18-19, 2025 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on October 1, 2025**.
April 2025	Notice of Proposed Rulemaking to be published in the Federal Register as mandated by the Omnibus Budget Reconciliation Act of 1986, Public Law 99-509 (Pub. L. 99-509). This notice will include references to the FY 2026 ICD-10-CM diagnosis and ICD-10-PCS procedure codes finalized to date. It will also include proposed revisions to the MS-DRG system based on ICD-10-CM/PCS codes on which the public may comment. The proposed rule can be accessed at: https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps
May 16, 2025	**Deadline for receipt of public comments on proposed new codes and revisions discussed at the March 18-19, 2025 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on April 1, 2026.**

	Deadline for receipt of public comments on proposed new diagnosis codes and revisions discussed at the March 18-19, 2025 ICD-10 Coordination and Maintenance Committee Meeting being considered for implementation on October 1, 2026.
May/June 2025	Final addenda posted on web pages as follows: **Diagnosis addendum -** https://www.cdc.gov/nchs/icd/icd-10-cm/files.html **Procedure addendum -** https://www.cms.gov/medicare/coding-billing/icd-10-codes
June 6, 2025	**Deadline for requestors: Those members of the public requesting that topics be discussed at the September 9-10, 2025 ICD-10 Coordination and Maintenance Committee Meeting must have their requests submitted to CMS for procedures and NCHS for diagnoses.** Requestors should indicate if they are submitting their code request for consideration for an April 1, 2026 implementation date or an October 1, 2026 implementation date. The ICD-10 Coordination and Maintenance Committee will make efforts to accommodate the requested implementation date for each request submitted, however, the Committee will determine which requests will be presented for consideration for an April 1, 2026 implementation date or an October 1, 2026 implementation date.
July 2025	Federal Register notice for the September 9-10, 2025 ICD-10 Coordination and Maintenance Committee Meeting will be published. This will include the tentative agenda.
August 2025	Hospital Inpatient Prospective Payment System final rule expected to be published in the Federal Register as mandated by Pub. L. 99-509. This rule will also include links to all the final codes to be implemented on October 1, 2025. This rule can be accessed at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html
August 2025	Tentative agenda for the Procedure portion of the September 9, 2025 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the CMS webpage at – https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html

	Tentative agenda for the Diagnosis portion of the September 10, 2025 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the NCHS webpage at – https://www.cdc.gov/nchs/icd/icd-10-maintenance/meetings.html
September 9-10, 2025	The September 2025 ICD-10 Coordination and Maintenance Committee Meeting is anticipated to be fully virtual by zoom and dial-in. Those who wish to attend must participate via Zoom Webinar or by dialing in.
September 2025	Recordings and slide presentations of the September 9-10, 2025 ICD-10 Coordination and Maintenance Committee Meeting will be posted on the following web pages: **Diagnosis code portion of the recording and related materials–** https://www.cdc.gov/nchs/icd/icd-10-maintenance/meetings.html **Procedure code portion of the recording and related materials–** https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.html
October 1, 2025	New and revised ICD-10-CM and ICD-10-PCS codes go into effect along with MS-DRG changes. Final addenda available on web pages as follows: **Diagnosis addendum –** https://www.cdc.gov/nchs/icd/icd-10-cm/files.html **Procedure addendum –** https://www.cms.gov/medicare/coding-billing/icd-10-codes

Introductions and Overview

- ICD-10 Coordination & Maintenance (C&M) Committee meeting is a public forum on ICD-10-CM & ICD-10-PCS code updates
- CMS & CDC Co-chair the meetings
  - CMS has lead responsibility on procedure issues
  - CDC has lead responsibility on diagnosis issues
- Coding proposals requested by the public are presented and public given opportunity to comment

Code Proposals

- ICD-10-PCS code proposals being considered for implementation on April 1, 2025 and October 1, 2025
- No final decisions are made at the meeting
- CMS will describe options and recommendations to facilitate discussion
- Public can comment during the meeting and send written comments

Comments on Code Proposals

- Submit written comments by
  - October 11, 2024 for codes being considered for April 1, 2025 implementation
  - November 15, 2024 for codes being considered for October 1, 2025 implementation
- Procedure comments to CMS: ICDProcedureCodeRequest@cms.hhs.gov
- Diagnosis comments to NCHS: nchsicd10cm@cdc.gov

Proposed and Final Rules

- April 2024 – Notice of Proposed Rulemaking, IPPS
  - Includes ICD-10-CM/PCS diagnosis and procedure updates approved prior to March 2024 C&M meeting

- August 2024 – Final rule with links to final codes to be implemented October 1, 2024
  - Includes any additional codes approved from March 19-20, 2024 C&M meeting
  - https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps

Addenda

- May/June 2024 – Final code updates and addendum posted
  - FY 2025 ICD-10-PCS (Procedures)
    https://www.cms.gov/medicare/coding-billing/icd-10-codes
  - FY 2025 ICD-10-CM (Diagnoses)
    https://www.cdc.gov/nchs/icd/icd-10-cm/files.html

Public Participation

- For this virtual meeting, the public may participate in the following ways:
  - Participate via Zoom Webinar
  - Listen to proceedings through free conference lines
  - Listen to recordings and view slide presentations
- CMS & CDC hope this provides greater opportunity for public participation

Written Comments

- No matter how you participate – please send written comments by
  - October 11, 2024 for codes being considered for April 1, 2025 implementation
  - November 15, 2024 for codes being considered for October 1, 2025 implementation
  - Procedure comments to CMS: ICDProcedureCodeRequest@cms.hhs.gov
  - Diagnosis comments to NCHS: nchsicd10cm@cdc.gov

ICD-10-PCS Codes Implementation

- ICD-10-PCS codes discussed today under consideration for April 1, 2025 or October 1, 2025 implementation

March 18-19, 2025 C&M Code Requests

- December 6, 2024 – Deadline for submitting topics for March 18-19, 2025 C&M meeting
  - Procedure requests to CMS: https://mearis.cms.gov
  - Diagnosis requests to NCHS: nchsicd10cm@cdc.gov

Topic # 01 – Transcatheter Bypass of Left Atrium to Right Atrium via Coronary Sinus

Issue: There are no unique ICD-10-PCS codes to describe transcatheter bypass of left atrium to right atrium via the coronary sinus. An April 1, 2025 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? No. The APTURE Transcatheter Shunt System (Edwards Lifesciences) received Breakthrough Device Designation on October 18, 2021. Per the requestor, an application for FDA Premarket Approval (PMA) approval is intended to be submitted after completion of a successful pivotal trial demonstrating the safety and efficacy of the technology.

Background: Heart failure impacts 64 million people worldwide[1] and is a leading cause of hospitalizations in North America and Europe.[2,3] Heart failure affects quality of life (QoL) more profoundly than many other chronic diseases. In cases where the left ventricular wall is thickened and stiff, the wall loses its ability to move outwards as the ventricle fills. Consequently, the pressure in the left ventricle increases, resulting in an increase in left atrium pressure because the blood in the left atrium is unable to flow into the ventricle. This pressure increase is eventually transferred backwards to the lungs. Over time this leads to various degrees of intimal thickening of the pulmonary veins and intermediate vessels, the severity of which correlates with the severity of increases in pulmonary artery pressure. Heart failure patients with pulmonary hypertension typically present with more severe symptoms including dyspnea on mild exertion, ascites, and peripheral edema. An echocardiogram is typically performed for diagnosis; however, a cardiac computed tomography scan and pulmonary artery wedge pressure measurements taken at rest and during an exercise stress test are also used to support a diagnosis.

Technology
The APTURE Transcatheter Shunt System is a self-expanding nitinol cardiovascular implant consisting of four arms including two left atrial (LA) arms and two coronary sinus (CS) arms. It is implanted between the left atrium and coronary sinus to create a 7mm flow diameter channel for blood to flow from the high-pressure region of the left atrium to the lower pressure region of the right atrium via the coronary sinus. The atrial shunt has five radiopaque tantalum markers located at the end of each of the proximal CS, proximal LA and distal LA arms. The atrial shunt is attached to the atrial shunt delivery catheter and housed under the outer sheath of the atrial shunt delivery catheter prior to insertion into the patient. The atrial shunt is a single implant device used to create a bypass from the left atrium to the right atrium via the coronary sinus. It is intended to be a permanent implant that is not removed. In the rare event a removal or revision is needed, it would require a separate open-heart or transcatheter procedure.

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[1] Gianluigi Savarese, Peter Moritz Becher, Lars H Lund, Petar Seferovic, Giuseppe M C Rosano, Andrew J S Coats, Global burden of heart failure: a comprehensive and updated review of epidemiology, *Cardiovascular Research*, Volume 118, Issue 17, December 2022, Pages 3272–3287, https://doi.org/10.1093/cvr/cvac013

[2] Salah HM, Minhas AMK, Khan MS, Pandey A, Michos ED, Mentz RJ, Fudim M. Causes of hospitalization in the USA between 2005 and 2018. Eur Heart J Open. 2021 Jun 15;1(1):oeab001. doi: 10.1093/ehjopen/oeab001. PMID: 35919090; PMCID: PMC9242058.

[3] OECD/European Union (2020), Health at a Glance: Europe 2020: State of Health in the EU Cycle, OECD Publishing, Paris, https://doi.org/10.1787/82129230-en.

Procedure Description
After general anesthesia is induced, the patient is intubated. A transesophageal echocardiography (TEE) probe is inserted and positioned to obtain appropriate views of the coronary sinus and left atrium. Right jugular vein access is obtained using conventional methods, and a guidewire is inserted prior to dilation of the access site.

The guide sheath is inserted over the guidewire into the right atrium and deflected towards the coronary sinus ostium. Fluoroscopic and echocardiographic guidance are used to cannulate the coronary sinus with a guidewire. The stabilizer is used to maintain positioning of the guide sheath. An angiographic marker catheter is advanced over the guidewire into the coronary sinus. Contrast is injected to acquire appropriate imaging to identify the target location for access into the left atrium and for placement of the shunt implant. The marker catheter is then exchanged for a stiff coronary sinus guidewire.

The access catheter is advanced over the guidewire into the coronary sinus. The needle is advanced into the left atrium to create access, which is confirmed using TEE. The needle is exchanged for a guidewire into the left atrium. A dilation balloon is inserted over the guidewire into the left atrium. The balloon is positioned across the shared wall between the coronary sinus and left atrium. The balloon is inflated to dilate the access hole created by the needle. The balloon is deflated and removed.

The implant system is inserted over the guidewire and advanced into the left atrium. After advancing the distal coronary sinus arm of the implant, a contrast shot is performed using fluoroscopy to confirm capture of the wall between the coronary sinus and left atrium. After confirmation, the shunt implant is released, and the implant delivery system is retracted and removed. Proper positioning and a functioning shunt is confirmed by TEE. The guide sheath is removed from the access site and the right jugular vein access is closed.

Current Coding: There are no unique ICD-10-PCS codes to describe transcatheter bypass of left atrium to right atrium via the coronary sinus. Code the procedure using the body part value 7 Atrium, Left, the device value J Synthetic Substitute, the percutaneous approach and the qualifier value 6 Atrium, Right in table 021, Bypass of Heart and Great Vessels.

Section	**0** Medical and Surgical		
Body System	**2** Heart and Great Vessels		
Operation	**1** Bypass: Altering the route of passage of the contents of a tubular body part		
Body Part	*Approach*	*Device*	*Qualifier*
7 Atrium, Left	**0** Open **4** Percutaneous Endoscopic	**8** Zooplastic Tissue **9** Autologous Venous Tissue **A** Autologous Arterial Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **Z** No Device	**P** Pulmonary Trunk **Q** Pulmonary Artery, Right **R** Pulmonary Artery, Left **S** Pulmonary Vein, Right **T** Pulmonary Vein, Left **U** Pulmonary Vein, Confluence
7 Atrium, Left	**3** Percutaneous	**J** Synthetic Substitute	**6** Atrium, Right

Coding Options

Option 1. Do not create new ICD-10-PCS codes for transcatheter bypass of left atrium to right atrium via the coronary sinus. Continue coding as described in current coding.

Option 2. In section X table X2K, Bypass of Heart and Great Vessels, create new device value 0 Conduit through Coronary Sinus to Right Atrium, applied to the body part value A Atrium, Left and the percutaneous approach, to identify transcatheter bypass of left atrium to right atrium via the coronary sinus.

Section	**X** New Technology		
Body System	**2** Cardiovascular System		
Operation	**K** Bypass: Altering the route of passage of the contents of a tubular body part		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
B Radial Artery, Right **C** Radial Artery, Left	**3** Percutaneous	**1** Thermal Resistance Energy	**7** New Technology Group 7
H Femoral Artery, Right **J** Femoral Artery, Left	**3** Percutaneous	**D** Conduit through Femoral Vein to Superficial Femoral Artery **E** Conduit through Femoral Vein to Popliteal Artery	**9** New Technology Group 9
ADD A Atrium, Left	**3** Percutaneous	**ADD 0** Conduit through Coronary Sinus to Right Atrium	**A** New Technology Group 10

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 02 – Administration of Roctavian™ (valoctocogene roxaparvovec-rvox)

Issue: There are no unique ICD-10-PCS codes to describe the administration of valoctocogene roxaparvovec-rvox. An October 1, 2025 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? Yes. A Biologics License Application (BLA) for valoctocogene roxaparvovec-rvox was approved on June 29, 2023 and is indicated for the treatment of adults with severe hemophilia A (congenital factor VIII deficiency with factor VIII activity <1 IU/dL) without pre-existing antibodies to adeno-associated virus serotype 5 detected by an FDA approved test.

Background: Hemophilia A is a condition of increased tendency to bleed due to inherited deficiencies of factor VIII, which disrupts the clotting cascade. Hemophilia A has X-linked recessive inheritance and predominately affects males. The exact prevalence of hemophilia in the United States (U.S.) is not known, but it is estimated to affect approximately 33,000 people. Patients with hemophilia A, particularly those with severe disease, are at risk for life-threatening bleeding, including intracranial bleeding. Patients with severe disease who are not receiving prophylactic treatment experience an average of 20 to 30 episodes of spontaneous bleeding or excessive bleeding after minor trauma per year. According to the requestor, living with uncertainty and chronic pain can lead to significant mental health issues (anxiety, depression, fatigue, substance use issues).

To reduce the risk of bleeding, patients with severe hemophilia have typically been administered or self-administer factor concentrate intravenously several times each week. Per the requestor, prophylaxis with factor replacement is burdensome to patients and their caregivers and does not maintain patients at normal levels of factor. There is a substantial time burden associated with prophylaxis, as patients must find time for infusions; this can be particularly challenging for caregivers of young and school-aged children. Caregivers of patients who receive infusions through a port must also monitor the port for infection, and such devices may also need to be periodically replaced, and, if they become infected, may require hospitalization for antibiotic treatment. Several factor preparations are available for prophylaxis, some prepared from human plasma, some prepared using recombinant technology including some with modifications to extend the half-life of the therapy. Many patients with hemophilia A now use emicizumab, a monoclonal antibody that can be administered monthly by subcutaneous injection, for prophylaxis in preference to factor VIII.

Per the requestor, the primary improvement from valoctocogene roxaparvovec-rvox is a reduction in the annualized bleeding rates (ABRs) over time. The bleeding rates reported in the GENEr8-1 trial reflect the change from baseline ABR during the 6-month run in phase when patients were on factor VIII prophylaxis. All the reductions were clinically and statistically significant. According to the requestor, a secondary, but important benefit of valoctocogene roxaparvovec-rvox is freedom from the need to inject factor VIII into a vein regularly.

Mechanism of Action
Valoctocogene roxaparvovec-rvox is an adeno-associated virus serotype 5 (AAV5) based gene therapy vector, designed to introduce a functional copy of a transgene encoding the B-domain

deleted SQ form of human coagulation factor VIII (hFVIII-SQ). Transcription of this transgene occurs within the liver, using a liver-specific promoter, which results in the expression of hFVIII-SQ. The expressed hFVIII-SQ replaces the missing coagulation factor VIII needed for effective hemostasis.

Inpatient Administration of valoctocogene roxaparvovec-rvox
Valoctocogene roxaparvovec-rvox is a sterile suspension for one-time intravenous infusion. Baseline testing is performed to select patients, including testing for pre-existing antibodies to adeno-associated virus serotype 5 (AAV5), factor VIII inhibitor presence, and liver health assessments. The recommended dose is 6 × 10^13 vector genomes (vg) per kg of body weight. The infusion is started at 1 mL/min using an infusion pump. If tolerated, the rate may be increased every 30 minutes by 1 mL/min up to a maximum rate of 4 mL/min.

Each vial contains an extractable volume of 8 mL of valoctocogene roxaparvovec-rvox at a concentration of 2 × 10^13 vector genomes (vg) per mL, and the following excipients: mannitol (20 mg/mL), poloxamer 188 (2.0 mg/mL), sodium chloride (8.2 mg/mL), sodium phosphate monobasic dihydrate (0.23 mg/mL), sodium phosphate dibasic dodecahydrate (3.05 mg/mL) and Water for Injection, USP.

In the phase 3 GENEr8-1 trial, the most significant harm following treatment with valoctocogene roxaparvovec-rvox was liver enzyme elevation requiring treatment with corticosteroids (n=106, 79.1%). The mean duration of corticosteroid treatment was 34.7 weeks. A total of 17.9% of participants had serious adverse events. Common adverse events included headaches (41%), nausea (38%), arthralgia (40%) and fatigue (30%). In the phase 1/2 trial of valoctocogene roxaparvovec-rvox, there was one grade 2 acinar cell carcinoma of the parotid gland assessed as not related to valoctocogene roxaparvovec by vector integration site analyses. In the phase 3 GENEr8-1 trial, one patient was diagnosed with acute lymphoblastic leukemia 3 years after receiving gene therapy, though not thought to be due to the therapy.

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of valoctocogene roxaparvovec-rvox. Facilities can report the intravenous administration of valoctocogene roxaparvovec-rvox using one of the following codes:

3E033GC	Introduction of other therapeutic substance into peripheral vein, percutaneous approach
3E043GC	Introduction of other therapeutic substance into central vein, percutaneous approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the intravenous administration of valoctocogene roxaparvovec-rvox. Continue coding as listed in current coding.

Option 2. Create new codes in section X, New Technology, to identify the intravenous administration of valoctocogene roxaparvovec.

Section	**X** New Technology		
Body System	**W** Anatomical Regions		
Operation	**0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD F** Valoctocogene Roxaparvovec-rvox	**B** New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as listed in current coding.

Topic # 03 – Temporary Transvenous Diaphragm Activation

Issue: There are currently no unique ICD-10-PCS codes to describe temporary transvenous diaphragm activation. An October 1, 2025 implementation date is being requested.

New Technology Application? Yes. The requestor intends to submit a New Technology Add-on Payment (NTAP) application for FY 2026 consideration.

Food & Drug Administration (FDA) Approval? No. Per the requestor, The Lungpacer® Diaphragm Pacing System marketed as the AeroPace® System was granted FDA Breakthrough Device Designation on May 4, 2016. An investigational device exemption (IDE) was granted on February 22, 2019. In addition, a premarket approval application (PMA) was submitted to the FDA on April 5, 2024.

Background: Difficult to wean mechanically ventilated (MV) patients have been defined as requiring 1-3 weaning attempts or up to 7 days to wean from the first weaning trial, and prolonged weaning as having failed > 3 weaning attempts or needing > 7 days to wean. The WIND study found 99% of MV patients could be classified based on days on MV only: the majority of patients weaned in < 24 hours (group 1), 10% had difficult weaning in < 7 days (group 2), and 9% required > 7 days (group 3).[1] Duration of ventilation, intensive care unit stay, and mortality (6, 17, and 29% for the three groups, respectively) all significantly increased from one group to the next.[1] About one-third of mechanically ventilated patients are in the indicated population of MV ≥ 4 days without being weaned.[1,2] The clinical and economic outcomes are significantly worse in this cohort of critically ill patients when compared with patients on MV < 4 days. Hospital mortality, extubating failure, tracheostomy, and the incidence of ventilator associated pneumonia are all higher in patients on MV ≥ 4 days.[2] Furthermore, after hospital care, patients on MV > 4 days are more likely to be discharged to hospice than patients on MV < 4 days.[2] These patients lack a viable treatment option to target the underlying reason for failure to wean, diaphragmatic atrophy, after 96 hours of mechanical ventilation. Temporary transvenous diaphragm activation is an investigational treatment intended to help strengthen the diaphragm, the large muscle beneath the lungs that plays an important part in breathing. While a patient is on MV, the diaphragm does not get much use, because the ventilator is doing the breathing. As with all muscles, when it is not used, the diaphragm can lose strength, which makes it harder for a person to be weaned from (or no longer need) the ventilator. The AeroPace® System is designed to stimulate the nerves that activate the diaphragm to keep it in 'shape' and may help people wean from the ventilator more quickly to regain independent breathing.

According to the requestor, patients treated with temporary transvenous diaphragm activation had a 35% risk reduction for remaining on MV by day 30, weaned 3 days faster, and had a 60% risk reduction for reintubation within 30 days compared with standard of care.

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[1] Béduneau, G., Pham, T., Schortgen, F., et al. (2017). Epidemiology of Weaning Outcome according to a New Definition. The WIND Study. Am J Respir Crit Care Med 195(6): 772-783. PMID: 27626706 DOI: 10.1164/rccm.201602-0320OC.

[2] Zilberberg, M. D., Nathanson, B. H., Ways, J., Shorr, A. F. (2020). Characteristics, Hospital Course, and Outcomes of Patients Requiring Prolonged Acute Versus Short-Term Mechanical Ventilation in the United States, 2014–2018*. Critical Care Medicine 48(11): 1587-1594. PMID: 00003246-202011000-00006 DOI: 10.1097/ccm.0000000000004525

Technology
The AeroPace® System is intended for temporary stimulation of the phrenic nerve(s) to increase diaphragmatic strength. According to the requestor, it is indicated to improve weaning success, reduce ventilator days, and reduce reintubation in patients 18 years and older who have received mechanical ventilation for ≥ 96 hours and who have not weaned. The technology consists of multiple components: the AeroPace® Neurostimulation Console, the AeroPace® Catheter and Catheter Cable, the Handheld Controller, and the Airway Sensor and Sensor Cable. The AeroPace® Neurostimulation Console contains software-controlled electronics, housed in an enclosure, that generate stimulation output that is transmitted from the console through the catheter cable to the electrodes on the AeroPace® catheter. The console includes a touchscreen monitor with a graphical user interface (GUI), allowing the operator to interact with and control the system. The system can also be controlled remotely by a handheld controller that has visual indicators for each of four procedural commands and connects to the console. The AeroPace® catheter is a sterile, single-use catheter with 30 electrodes (arranged in two arrays to stimulate the left and right phrenic nerves) and can be inserted into either the left subclavian vein or the left jugular vein. An intravascular electrogram display is provided to assist with catheter placement. The technology also includes the airway sensor with sensor cable, which detects and communicates pressure data to the console, and is used for automated placement, mapping and therapy. Stimulation settings relative to the stimulation threshold (the minimal stimulation level to elicit diaphragm activation) are adjusted manually by the operator. Stimulations can be delivered in manual or auto mode.

Procedure Description
Per the requestor, temporary transvenous diaphragm activation is performed in an inpatient hospital setting in a minimally invasive manner at the bedside in sedated and non-sedated critically ill patients, all of whom are at high risk of ventilator-induced diaphragm dysfunction (VIDD).The catheter is inserted into the left jugular vein or left subclavian vein using the standard Seldinger technique, with the catheter tip placed in the distal superior vena cava (SVC), 1-2 cm above the level of the carina. Catheter placement confirmation is conducted by verifying that left-side electrodes elicit diaphragmatic contractions by detecting pressure data communicated by the airway sensor (auto mode), or by manual palpation/observation (manual mode). Once the placement of left-side electrodes is confirmed, institutional practice (e.g., X-ray) is utilized to confirm the appropriate placement of the catheter.

Electrode mapping is then performed to identify suitable combinations of electrodes to recruit the left and/or right phrenic nerves and elicit diaphragm activations. Mapping is performed using pressure data from the airway sensor or by manual palpation/observation. Mapping determines the minimum energy needed to recruit the left and right hemidiaphragms (stimulation threshold). Diaphragmatic contractions are delivered to exercise the diaphragm muscle while the patient is on any mode of ventilation. The airway sensor detects and communicates pressure data to initiate stimulation just after the start of inspiration. Stimulations can also be delivered manually. The exclusion function of the AeroPace® System is used as needed during therapy to temporarily disable electrodes that cause unwanted stimulation. Each session for mapping and delivery of therapy generally is conducted within 10 to 30 minutes. Temporary transvenous diaphragm activation is delivered in 6 sets of 10 stimulations, twice daily for a total of 120 stimulations/day for up to 30 days. The catheter is removed upon successful weaning or after 30 days. The AeroPace® catheter is single use. If the catheter needs to be removed and replaced, a new catheter may be inserted within the 30-day treatment period.

According to the requestor, in clinical trials there were no unanticipated serious adverse device events (USADE). The most frequent device- or procedure-related adverse events (AE) and serious adverse events (SAE) were infections, cardiac disorders, and vascular disorders. Infections were catheter-related infection, bacteremia or sepsis, and vascular AEs were related to catheter placement such as hemothorax, pneumothorax, acute coronary syndrome due to tension pneumothorax or deep vein thrombosis. Inadvertent temporary cardiac stimulation (arrythmia) accounted for 1.8% of SAEs, while 0.9% of SAEs were related to catheter misplacement or transvenous stimulation. Post-procedural pain was related to stimulation. Among serious adverse events (SAEs) deemed device- or procedure-related, the most frequently reported were infections and cardiac disorders. The requestor confirmed the two deaths that occurred were associated with SAEs in the clinical trials, and that AEs were consistent with those anticipated for Intensive Care Unit (ICU) patients receiving MV. Additionally, AEs related to the catheter were within expected incidences. AEs related to transvenous stimulation were temporary, low incidence, and managed without sequelae.

Current Coding: There are no unique ICD-10-PCS codes to describe temporary transvenous diaphragm activation. Code the procedure using the body part value V Superior Vena Cava, the device value Y Other Device, and the percutaneous approach in table 02H, Insertion of Heart and Great Vessels.

Section	**0** Medical and Surgical		
Body System	**2** Heart and Great Vessels		
Operation	**H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part		
Body Part	*Approach*	*Device*	*Qualifier*
P Pulmonary Trunk **Q** Pulmonary Artery, Right **R** Pulmonary Artery, Left **S** Pulmonary Vein, Right **T** Pulmonary Vein, Left **V** Superior Vena Cava	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**0** Monitoring Device, Pressure Sensor **2** Monitoring Device **3** Infusion Device **D** Intraluminal Device **Y** Other Device	**Z** No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes for temporary transvenous diaphragm activation. Continue coding as listed in current coding.

Option 2. In section X table X2H, Insertion of Heart and Great Vessels, create new device value X Temporary Phrenic Nerve/Diaphragm Stimulation Electrodes, applied to the body part value 1 Superior Vena Cava and the percutaneous approach, to identify temporary transvenous diaphragm activation.

Section **X** New Technology *Body System* **2** Cardiovascular System *Operation* **H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part			
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
0 Inferior Vena Cava **1** Superior Vena Cava	**3** Percutaneous	**R** Intraluminal Device, Bioprosthetic Valve	**9** New Technology Group 9
2 Femoral Vein, Right **3** Femoral Vein, Left	**0** Open	**R** Intraluminal Device, Bioprosthetic Valve	**9** New Technology Group 9
6 Atrium, Right **K** Ventricle, Right	**3** Percutaneous	**V** Intracardiac Pacemaker, Dual-Chamber	**9** New Technology Group 9
L Axillary Artery, Right **M** Axillary Artery, Left **X** Thoracic Aorta, Ascending	**0** Open	**F** Conduit to Short-term External Heart Assist System	**9** New Technology Group 9
1 Superior Vena Cava	**3** Percutaneous	**ADD X** Temporary Phrenic Nerve/Diaphragm Stimulation Electrodes	**B** New Technology Group 11

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using current codes as listed in current coding.

Topic # 04 – Insertion of Endovascular Anchors

Issue: There are no unique ICD-10-PCS codes to describe the insertion of endovascular anchors in initial endovascular aortic aneurysm repair (EVAR) or in revision of prior endovascular aortic aneurysm repair. An October 1, 2025 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? Yes. The endovascular anchor model currently available in the U.S. initially received marketing authorization from the FDA on November 21, 2011, via the de novo pathway. Since that time, six additional 510(k) submissions have been cleared for device modifications and line extensions, most recently on November 21, 2018. The endovascular anchor is designated a device by the FDA and cleared by its Division of Cardiovascular Devices, Office of Device Evaluation, Center for Devices and Radiological Health.

Background: Endovascular anchors are used in the treatment of aortic aneurysms as well as to treat complications of prior EVAR procedures. Complications of EVAR procedures which endovascular anchors are used to treat include endograft migration, endoleak, and failure of the aneurysm sac to regress (shrink).

Typically, endovascular anchors are used with a subset of aortic aneurysms, specifically those with hostile neck anatomy. Hostile neck anatomy for aortic aneurysm includes:
- Short proximal aneurysm neck (<15 mm) which leads to reduced infrarenal sealing zone
- Wide aneurysm neck (≥28mm) which is statistically more prone to endoleak
- Angulated aneurysm neck (≥60% degrees) for which "bird-beaking" interferes with proximal sealing
- Conical aneurysm neck (progressive increases in diameter between the renal arteries and the aneurysm sac) which is more prone to graft migration and endoleak

Hostile neck anatomy increases the complexity of EVAR procedures and increases the risk of suboptimal outcomes and complications such as type Ia endoleaks and aneurysm-related mortality. According to the requestor, for hostile neck anatomy in general, there is a 4.5x increased risk of type 1a endoleak and a 10x increased risk of aneurysm-related mortality. More specifically, wide aneurysm neck is 6.7x more likely to have a type 1a endoleak, 10x more likely to have aneurysm sac expansion, and 5.1x more likely to lead to aneurysm rupture.

Use of endovascular anchors in hostile neck anatomy shows distinct and improved therapeutic clinical outcomes. Registry data for use of endovascular anchors over 3 years demonstrate multiple improved outcomes for wide neck aneurysms including 98.5% freedom from type 1a endoleaks, 100% freedom from endograft migration, 100% freedom from aneurysm rupture, and 60% aneurysm sac regression and 30% aneurysm sac stability. Similarly, registry data for use of endovascular anchors over 5 years demonstrate multiple improved outcomes for short neck aneurysms, including 90% freedom from aneurysm-related mortality, 77% freedom from reinterventions, and 68% aneurysm sac regression and 13.6% aneurysm sac stability.

Technology
Per the requestor, endovascular anchors were initially designed to mimic the effect of surgical sutures used in "gold standard" open aortic aneurysm graft repair, leading to the false impression that these implants are sutures. Endovascular anchors are used in the treatment of aortic aneurysms by providing fixation and sealing between endografts and the aorta. The majority of endografts placed to treat aortic aneurysms are held in place by the passive outward radial (i.e., circumferential) force of the endograft itself or of its cuffs or extensions. Many aortic endografts also feature small pins in their frames which passively engage the aortic tissue. In contrast, endovascular anchors are metallic helical implants that provide augmented transmural radial fixation. They extend completely through both the endograft and the wall of the aorta. There is anchoring on both sides, with the endovascular anchor flush with the lumen of the endograft and the outer wall of the aorta, to create an active seal.

The endovascular anchor system is composed of a guide catheter, an applier which serves as the delivery catheter for the endovascular anchors, and the endovascular anchors supplied in a pre-loaded cassette. The system is compatible for use with endovascular aortic aneurysm endografts from multiple manufacturers. The endovascular anchors are the only permanent implant.

According to the requestor, the insertion of endovascular anchors has its own distinct clinical outcomes. Due to the heart's continual pulsing, the passive outward radial force that endografts rely on does not arrest dilatation of the aorta and in fact can further contribute to aneurysm neck dilatation. However, endovascular anchors have been shown to protect against this and are associated with significant reduction in type 1a endoleaks. Use of endovascular anchors in initial EVAR also markedly improves regression of the aneurysm sac, which is associated with lower mortality, lower morbidity, and lower need for reintervention.

Procedure Description
Access is typically through the femoral artery. In an initial EVAR procedure, after the endograft is placed, the same femoral access is used to deliver the endovascular anchors. In a revision EVAR procedure, femoral artery access is established to deliver the anchors.

The procedure can be performed in the abdominal aorta for abdominal aortic aneurysms and in the descending thoracic aorta for thoracic aortic aneurysms. Under fluoroscopic guidance, a guidewire is advanced to the aorta, through the endograft, and into the proximal endograft seal zone. This is followed by the guide catheter. Each endovascular anchor is loaded onto the applier delivery catheter which is then advanced through working channel of the guide catheter. After positioning is checked, each endovascular anchor is individually deployed through the inner wall of the endograft and across the aorta. As needed, the endovascular anchor can be retracted and repositioned prior to final deployment. All endovascular anchors are individually placed using the same applier.

Between 4 and 10 endovascular anchors are individually placed, with 6 being the typical number. This number varies based on the anatomy and type of aneurysm. Because the endovascular anchors work in concert, it is not necessary or useful to identify the number implanted.

Endovascular anchor insertion is adjunctive to placement of the aortic endograft when performed with an initial endovascular aortic aneurysm repair. When performed for revision of a prior

endovascular aortic aneurysm repair, it is typically a stand-alone procedure. The endovascular anchors are permanent implants.

Current Coding: There are no unique ICD-10-PCS codes to identify the insertion of endovascular anchors in the context of EVAR procedures. Facilities would report the appropriate code for the initial EVAR procedure or additional revision of EVAR if performed.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the insertion of endovascular anchors in the context of EVAR procedures. Continue coding as described in current coding.

Option 2. In the Medical and Surgical section tables 02U and 04U Supplement of Heart and Great Vessels and Supplement of Lower Arteries, respectively, create new device value L Intraluminal Device, Endovascular Anchors applied to the body part values W Thoracic Aorta, Descending and 0 Abdominal Aorta, applied to the percutaneous approach, to identify the placement of endovascular anchors. Continue to report the appropriate code for the EVAR procedure or additional revision of EVAR if performed.

Section **0** Medical and Surgical *Body System* **2** Heart and Great Vessels *Operation* **U** Supplement: Putting in or on biological or synthetic material that physically reinforces and/or augments the function of a portion of a body part			
Body Part	*Approach*	*Device*	*Qualifier*
W Thoracic Aorta, Descending	**3** Percutaneous	**7** Autologous Tissue Substitute **8** Zooplastic Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **ADD L** Intraluminal Device, Endovascular Anchors	**Z** No Qualifier

Section **0** Medical and Surgical *Body System* **4** Lower Arteries *Operation* **U** Supplement: Putting in or on biological or synthetic material that physically reinforces and/or augments the function of a portion of a body part			
Body Part	*Approach*	*Device*	*Qualifier*
0 Abdominal Aorta	**3** Percutaneous	**7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute **ADD L** Intraluminal Device, Endovascular Anchors	**Z** No Qualifier

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 05 – External Fixation with Automated Strut Adjustment

Issue: There are no unique ICD-10-PCS codes to describe the attachment of a hexapod ring-fixation system with automated strut adjustment. An April 1, 2025 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? Yes. The MAXFRAME AUTOSTRUT™ System has two clearances. The first clearance date was January 6, 2021 under 510(k) number K202810 (submitted under Orthospin Ltd., prior to the Johnson & Johnson (J&J) acquisition). The second clearance date was July 26, 2023 under 510(k) number K231922 (DePuy Synthes).

Background: Within the field of orthopedic trauma, options for treating affected anatomy (e.g., femur, tibia, humerus, radius and ulna) include either open reduction internal fixation (ORIF) where a device is placed on or around the bone, or an external fixation device that uses pins inserted into bone and the forces placed on the bone from outside the patient body engender bone healing. A hexapod ring fixator (HRF) is a type of external fixation device that consists of circular carbon fiber, or stainless-steel frames secured to the patient with implantable pins and devices called struts that attach to the frame and may be adjusted to apply force to the device to move bone fragments internally during the healing process. Surgeons may use HRF on long bones to treat several conditions, including fracture, deformity correction, limb lengthening, osteomyelitis, and segmental defects that arise from excision of bone tissue because of trauma or osteosarcoma.

Ring fixators are used in a small proportion of patients. A retrospective claims analysis identified 1,867 patients fitted with hexapod ring fixation systems from 2017-2019 using the Premier Hospital Perspective™ Billing Database. Per the requestor, patients that use manual external ring-fixation can be highly complex to manage and can have significant burdens associated with their treatment journey. For example, patients and caregivers may struggle with manually adjusting the struts on their external ring–fixation frames. In addition, errors in adherence to the daily strut adjustment treatment plan can lead to more follow-up visits, x-rays, non-unions, re-operations, and patient dissatisfaction. Smaller, more frequent strut adjustments may be better for surrounding soft tissue, reduce pain, and improve the quality of the bone regenerate versus larger and less frequent strut adjustments.

Technology
The MAXFRAME AUTOSTRUT™ Multi-Axial Correction System uses automated struts generated by a controller instead of manual strut adjustments the patient generates directly. It enables smaller, more frequent adjustments (up to 20 times per day versus 1-2 times per day of manually adjusting struts) to reduce pain associated with fewer daily adjustments. It is considered a medical device that is mainly external to the body. The only "implant" component of the device consists of the pins inserted into the patient's bone to anchor the frame. Generally, one frame addresses a bone defect. However, should a patient have multiple bone defects (e.g., bilateral tibial deformity correction), a frame could be placed independently on each leg.

The MAXFRAME AUTOSTRUT™ System is indicated for the following treatments in adults, and in both children (ages 3–12) and adolescents (ages 12-21) in which growth plates have fused or will not be crossed with hardware: fracture fixation (open and closed), pseudoarthrosis of long bones, limb lengthening (epiphyseal or metaphyseal distraction), joint arthrodesis, infected fractures or nonunion, correction of bony or soft tissue deformities, and correction of segmental defects.

The system utilizes the existing MAXFRAME™ technology and consists of both hardware and software components as follows:
1. Automated hexapod struts are used in place of manual struts and are attached to the circular frame portion of the device.
2. The Automated Hexapod Control System Kit consists of a control system unit with a wired connection to the six motorized struts. The exterior of the unit is plastic, water resistant (patient may shower with device on) and attaches to the circular portion of the HRF. These struts apply forces to the bone the same way that standard struts would, however, they are adjusted through the control system and not by the patient directly.
3. Software running inside the Automated Hexapod Control System allows physicians to download the treatment plan to the device, chart patient progress, and, if required, adjust the treatment plan and schedule.

According to the requestor, patients no longer need to manipulate the struts, leading to an improved experience throughout the treatment, and reducing the risk of negative clinical outcomes caused by unintended strut adjustments.

Procedure Description
The surgeon first addresses the bone defect (e.g., reduces fracture, performs osteotomy) and then inserts pins into the patient's bone segments. If the procedure is open, the patient's wound is closed. The surgeon assembles the MAXFRAME™ multi-axial ring fixation frame on the patient in the operating room and the MAXFRAME AUTOSTRUT™ hexapod struts (automated struts) are attached to the frame. MAXFRAME AUTOSTRUT™ hexapod struts are designed to shorten and lengthen according to the treatment regimen prescribed by the physician. MAXFRAME AUTOSTRUT™ struts are compatible with MAXFRAME™ hardware (ring sizes 90–270 mm). Three sizes of MAXFRAME AUTOSTRUT™ hexapod struts are available – short, medium and long.

Once the patient is out of the operating room and in recovery, the surgeon attaches the MAXFRAME AUTOSTRUT™ control system unit onto the frame and connects the control unit wires to each automated strut. The surgeon tests that the control unit can communicate via the software prior to discharge. The system is activated by attaching a computer running MAXFRAME AUTOSTRUT™ Software to the main control box via a USB cable. The provider then uploads their patient-specific strut adjustment plan to the MAXFRAME AUTOSTRUT™ Control System. The Control System is one integrated unit including the control box and all attached motors. All components needed for installation are provided in the Control System Kit. The control box ring interface is attached to any free space near the master tab of the MAXFRAME™ with two Allen screws by using a 3mm Allen key. The control box with six motors attached is slid onto the box interface until it clicks in place and cannot slide back. Two cable splitters are snapped into place on the upper ring on any free space near the connection with the side struts, as close to the box as possible. The six motors are inserted into the adjacent strut motor adaptors and secured with motor

clips. A snap cable wrapper is placed in a free space on both sides of the upper ring to wrap any excess cable.

The patient is discharged and returns to the clinic for follow-up. With each visit, the surgeon can evaluate the progress of the correction by connecting a computer running MAXFRAME AUTOSTRUT™ software to the patient via USB.

According to published literature, this type of external fixation system is used for a variable duration of time with an average range of 96-104 days based on diagnostic category (i.e. deformity, fracture, infection, non-union, etc.) and removed after the treatment plan is complete. All internal and external components including pins are removed.

Current Coding: There are no unique ICD-10-PCS codes to identify the attachment of a hexapod ring-fixation system with automated strut adjustment. Code the procedure in the Medical and Surgical section tables 0PH or 0QH, Insertion of Upper Bones or Insertion of Lower Bones, using the device value C External Fixation Device, Ring, with the applicable body part value and the approach value 0 Open. Assign codes as appropriate for any additional procedures performed such as fracture reduction or osteotomy of bone deformity.

Section	**0** Medical and Surgical		
Body System	**P** Upper Bones		
Operation	**H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part		
Body Part	*Approach*	*Device*	*Qualifier*
0 Sternum	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**0** Internal Fixation Device, Rigid Plate **4** Internal Fixation Device	**Z** No Qualifier
1 Ribs, 1 to 2 **2** Ribs, 3 or More **3** Cervical Vertebra **4** Thoracic Vertebra **5** Scapula, Right **6** Scapula, Left **7** Glenoid Cavity, Right **8** Glenoid Cavity, Left **9** Clavicle, Right **B** Clavicle, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**4** Internal Fixation Device	**Z** No Qualifier
C Humeral Head, Right **D** Humeral Head, Left **H** Radius, Right **J** Radius, Left **K** Ulna, Right **L** Ulna, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**4** Internal Fixation Device **5** External Fixation Device **6** Internal Fixation Device, Intramedullary **8** External Fixation Device, Limb Lengthening **B** External Fixation Device, Monoplanar **C** External Fixation Device, Ring **D** External Fixation Device, Hybrid	**Z** No Qualifier
F Humeral Shaft, Right	**0** Open **3** Percutaneous	**4** Internal Fixation Device **5** External Fixation Device **6** Internal Fixation Device, Intramedullary	**Z** No Qualifier

G Humeral Shaft, Left	**4** Percutaneous Endoscopic	**7** Internal Fixation Device, Intramedullary Limb Lengthening **8** External Fixation Device, Limb Lengthening **B** External Fixation Device, Monoplanar **C** External Fixation Device, Ring **D** External Fixation Device, Hybrid	
M Carpal, Right **N** Carpal, Left **P** Metacarpal, Right **Q** Metacarpal, Left **R** Thumb Phalanx, Right **S** Thumb Phalanx, Left **T** Finger Phalanx, Right **V** Finger Phalanx, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**4** Internal Fixation Device **5** External Fixation Device	**Z** No Qualifier
Y Upper Bone	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**M** Bone Growth Stimulator	**Z** No Qualifier

Section *Body System* *Operation*	**0** Medical and Surgical **Q** Lower Bones **H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part		
Body Part	*Approach*	*Device*	*Qualifier*
0 Lumbar Vertebra **1** Sacrum **2** Pelvic Bone, Right **3** Pelvic Bone, Left **4** Acetabulum, Right **5** Acetabulum, Left **D** Patella, Right **F** Patella, Left **L** Tarsal, Right **M** Tarsal, Left **N** Metatarsal, Right **P** Metatarsal, Left **Q** Toe Phalanx, Right **R** Toe Phalanx, Left **S** Coccyx	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**4** Internal Fixation Device **5** External Fixation Device	**Z** No Qualifier
6 Upper Femur, Right **7** Upper Femur, Left **B** Lower	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**4** Internal Fixation Device **5** External Fixation Device **6** Internal Fixation Device, Intramedullary **8** External Fixation Device, Limb Lengthening **B** External Fixation Device, Monoplanar	**Z** No Qualifier

Femur, Right **C** Lower Femur, Left **J** Fibula, Right **K** Fibula, Left		**C** External Fixation Device, Ring **D** External Fixation Device, Hybrid	
8 Femoral Shaft, Right **9** Femoral Shaft, Left **G** Tibia, Right **H** Tibia, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**4** Internal Fixation Device **5** External Fixation Device **6** Internal Fixation Device, Intramedullary **7** Internal Fixation Device, Intramedullary Limb Lengthening **8** External Fixation Device, Limb Lengthening **B** External Fixation Device, Monoplanar **C** External Fixation Device, Ring **D** External Fixation Device, Hybrid	**Z** No Qualifier
Y Lower Bone	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**M** Bone Growth Stimulator	**Z** No Qualifier

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the attachment of a hexapod ring-fixation system with automated strut adjustment. Continue coding as described in current coding.

Option 2. In the Medical and Surgical section tables 0PH and 0QH Insertion of Upper Bones and Insertion of Lower Bones, create new device value F Ring External Fixation Device with Automated Strut Adjustment applied to the long bone body part values and the open approach, to identify the attachment of a hexapod ring-fixation system with automated strut adjustment. Continue to assign codes as appropriate for any additional procedures performed such as fracture reduction or osteotomy of bone deformity.

Section	**0** Medical and Surgical
Body System	**P** Upper Bones
Operation	**H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part

Body Part	*Approach*	*Device*	*Qualifier*
F Humeral Shaft, Right **G** Humeral Shaft, Left **H** Radius, Right **J** Radius, Left **K** Ulna, Right **L** Ulna, Left	**0** Open	**ADD F** Ring External Fixation Device with Automated Strut Adjustment	**Z** No Qualifier

Section	**0** Medical and Surgical
Body System	**Q** Lower Bones
Operation	**H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part

Body Part	*Approach*	*Device*	*Qualifier*
8 Femoral Shaft, Right **9** Femoral Shaft, Left **G** Tibia, Right **H** Tibia, Left	**0** Open	**ADD F** Ring External Fixation Device with Automated Strut Adjustment	**Z** No Qualifier

Option 3. In section X table XNH, Insertion of Bones, create new device value G Ring External Fixation Device with Automated Strut Adjustment, applied to the long bone body part values and the open approach, to identify the attachment of a hexapod ring-fixation system with automated strut adjustment. Continue to assign codes as appropriate for any additional procedures performed such as fracture reduction or osteotomy of bone deformity.

Section	**X** New Technology
Body System	**N** Bones
Operation	**H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
6 Pelvic Bone, Right **7** Pelvic Bone, Left	**0** Open **3** Percutaneous	**5** Internal Fixation Device with Tulip Connector	**8** New Technology Group 8
G Tibia, Right **H** Tibia, Left	**0** Open	**F** Tibial Extension with Motion Sensors	**9** New Technology Group 9
ADD 6 Humeral Shaft, Right **ADD 7** Humeral Shaft, Left **ADD 8** Radius, Right **ADD 9** Radius, Left **ADD B** Ulna, Right **ADD C** Ulna, Left **ADD D** Femoral Shaft, Right **ADD F** Femoral Shaft, Left **G** Tibia, Right **H** Tibia, Left	**0** Open	**ADD G** Ring External Fixation Device with Automated Strut Adjustment	**A** New Technology Group 10

CMS Recommendation: CMS is seeking input from the audience.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 06 – Extracorporeal Interstitial Fluid Removal

Issue: There are no unique ICD-10-PCS codes to describe extracorporeal interstitial fluid removal using a wearable garment. An April 1, 2025 implementation date is being requested.

New Technology Application? Yes. The requestor intends to submit a New Technology Add-on Payment (NTAP) application for FY 2026 consideration.

Food & Drug Administration (FDA) Approval? No. According to the requestor, AquaPass Systems received Breakthrough Device Designation for the indications of reducing fluid overload in patients with chronic heart failure or with chronic kidney disease stages 2-3 that are not responding adequately/resistant to current medical treatment and removing fluids in end stage renal disease patients, resulting in reduced fluid overload and ultrafiltration rates on December 9, 2022, and February 7, 2024, respectively.

Background: According to the requestor, the AquaPass System addresses two highly prevalent diseases in the United States (U.S.); congestive heart failure (CHF) and renal failure, by providing a solution to a substantial clinical challenge – the management of fluid overload. In the U.S., 35.5 million people have kidney disease. About 808,000 Americans are living with kidney failure. More than 557,000 Americans are on dialysis. It is estimated that 6.5 million people in the U.S. have congestive heart failure. It is the leading cause of hospitalization in people older than 65, with over 1 million hospitalizations per year. Persistent volume overload and congestion are the most common problems in renal and heart failure. The accumulation of fluids can be life-threatening and require advanced care in the hospital.

A mechanism for dissipating heat in humans involves the evaporation of sweat produced by sweat glands. Sweat production is triggered when exposed to higher environmental temperatures. The activity of sweat glands and the rate of sweat secretion are influenced by local skin temperature. Sweating can commence at a skin temperature as low as 33°C and within a temperature range of 33°C-40°C, the upper limit being set to prevent local skin burns. It is anticipated that individuals will excrete over 100 mL/hr of sweat solely due to a localized increase in skin temperature. Per the requestor, this method of augmenting sweat rate through elevating skin temperature may prove advantageous for patients experiencing fluid overload, as the expelled sweat originates from the interstitial compartment, where most excess fluid resides. Additionally, the clinical requirement for a meaningful fluid removal rate exceeding 100 mL/hr can be met by subjecting the patient's torso and lower body to elevated temperatures, achieving skin temperatures above 33°C but much lower than 40°C. Through the induction of heat, AquaPass provides a uniform and efficient heat distribution over the patient's body. This thermal activation is continuously monitored to maintain user safety and optimal treatment.

Technology
Per the requestor, AquaPass is designed to facilitate the extraction of excess interstitial fluid in patients suffering from fluid overload attributed to conditions such as congestive heart failure or end stage renal disease (ESRD). This is achieved through a natural and controlled process that activates the sweating system, effectively removing fluids from the interstitial compartment. The AquaPass System establishes microclimate conditions in proximity to the patient's skin to optimize this process. The device includes two main components: (1) a control station and (2) a wearable garment. These components are connected via an air passage tube equipped with

sensors that actively monitor vital indicators. The attending physician sets patient-specific parameters based on the desired fluid removal rate.

(1) The control station is a portable, movable unit that can be used repeatedly with cleaning in between uses. It houses a heat pump, a control system, and an air passage tube that is attached to the wearable garment. The heat pump transfers heated air at a rate of 1 to 1.6m3/min. This air is directed through the wearable garment's tube, ensuring the contact surface between the treated skin and clothing remains within the targeted temperature range of 38-46°C inside the wearable garment, maintaining normal skin temperature. A precise flow meter measures the airflow, while a temperature safety sensor regulates the air temperature before it exits the hose. Sensors in the wearable garment measure blood pressure, heart rate, and core temperature, which are used to monitor and adjust the patient's treatment.

(2) The wearable garment is a device designed for a single patient to use multiple times, up to 10 uses per patient. It covers the patient from the upper torso down to the feet and is engineered to disperse hot air evenly around the patient's body, fostering a controlled and comfortable treatment environment that induces controlled skin temperature elevation and sweat production. Designed from a biocompatible 100% polyester, the wearable garment features two fabric sheets that contain an intricate network of air channels. This design optimizes air distribution, allowing a uniform flow from the upper body wearable garment area to the designated air outlets at the lower extremities. The device includes a laminated layer of thermoplastic polyurethane (TPU) between the fabric sheets to repel liquids and is coated with an antibacterial additive for infection prevention. Adjustable chest and shoulder straps enhance compatibility with diverse body structures, preventing unwanted airflow toward the neck and head. Strategic spaces in the back area facilitate airflow while sitting or lying down. The wearable garment is available in 3 sizes to accommodate different body structures.

Procedure Description
The AquaPass System is intended for inpatient hospital-based treatment. A physician orders the treatment based on the desired fluid removal rate. The patient is provided with the control station and the wearable garment. Once the patient puts on the garment, it is then connected to the control station with the air passage tube, the patient-specific temperature and time are then entered into the control station by the clinician. The patient will wear the garment for approximately 4 hours, during which they can sit, lay down, or ambulate for short distances.

According to the requestor, during the treatment, the 2-4 million eccrine glands secrete interstitial fluid with meaningful concentrations of nitrogenous wastes (urea, ammonia, lactate), electrolytes, heavy metals and minerals. These glands are activated by the elevation of skin temperature and the resulting production of sweat, which removes fluids directly from the interstitial compartment at rates equivalent to normal kidney function. Instantaneous evaporation of the removed fluids from the skin cools the cutaneous circulation, thereby maintaining normal core temperature and keeping the patient dry and comfortable. The use of the device results in a method of decongestion in patients with congestive heart failure or chronic kidney disease that is noninvasive and renal independent, causing fewer hypotension episodes than current renal dependent therapies. The requestor maintains that clinical trials demonstrated use of the AquaPass System in 40 fluid overloaded patients (CHF and/or ESRD) is safe and clinically meaningful, with an average >850 ml of fluid removed per 4-hour treatment, a 30% reduction in diuretic dosage, 0% 180-day mortality, 0% 30-day heart failure readmissions, and a 46% improvement in quality of life. The

requestor confirms there is an extremely slight risk of burn, and a slight potential for overheating. To date, there have been no serious adverse events, sequelae, or complications with the use of the AquaPass System.

Current Coding: There are no unique ICD-10-PCS codes to describe extracorporeal interstitial fluid removal using a wearable garment.

Coding Options

Option 1. Do not create new ICD-10-PCS codes for extracorporeal interstitial fluid removal using a wearable garment. Continue coding as listed in current coding.

Option 2. In section X table XXA, Assistance of Physiological Systems, create new technology value 7 Transpiration, Interstitial Fluid with Wearable Garment, applied to the body part value H Integumentary and the external approach, to identify extracorporeal interstitial fluid removal using a wearable garment.

Section	**X** New Technology		
Body System	**X** Physiological Systems		
Operation	**A** Assistance: Taking over a portion of a physiological function by extracorporeal means		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
ADD H Integumentary	**X** External	**ADD 7** Transpiration, Interstitial Fluid with Wearable Garment	**A** New Technology Group 10

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using current codes as listed in current coding.

Topic # 07 – Intraoperative Donor Organ Protection in Renal Transplantation

Issue: There are no unique ICD-10-PCS codes to describe the use of a protective insulation device on the donor kidney graft during renal transplantation. An October 1, 2025 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? No. The requestor anticipates receiving 510K clearance in January 2026.

Background: Kidney transplantation is a distinct procedure. There are numerous technical, medical and surgical steps that contribute to the renal transplant procedure. For the kidney transplantation to occur in a carefully chosen recipient, the donated kidney must be surgically harvested from a living or deceased donor. The graft is then transported to the operative site where the kidney transplant will take place. The donor kidney graft transport process adheres to strict procedures to protect the donor graft with established cooling methods that insure a static, hypothermic environment for the donor kidney.

During the renal transplant procedure, the previously cooled donor kidney is subjected to increased temperatures from the patient's body and the operative suite. Graft heat gain or warming (also referred to as thermal injury) can cause ischemia. Heat gain is clinically referred to as second warm ischemic time (SWIT). SWIT can cause postoperative delayed graft function (DGF). DGF exhibits in postoperative renal transplant patients as oliguria (decreased urine output) and laboratory results consistent with acute kidney injury (AKI). Post-transplant AKI from DGF is treated with medications and post-transplant hemodialysis. According to the requestor, there is no prevalent technology or device in practice to prevent donor kidney thermal injury during implantation.

In addition to causing immediate postoperative AKI from delayed graft function, the constant threat of kidney damage from heat gain can affect surgical performance. Per the requestor, transplant surgeons always strive to perform the operation as fast as possible to minimize kidney damage. Time-pressure can adversely affect the quality of surgery. In one-third of the cases, surgical complications are the most frequent cause of early graft loss after kidney transplantation.[1] The survival benefit (longevity) of the transplanted kidney allograft can also be impacted negatively by delayed graft function occurring immediately post-transplant. Premature renal graft failure may require the patient to resume dialysis. The previously transplanted recipient may then need a repeat transplant. The requestor performed their own analysis of data from the Centers for Medicare and Medicaid Services (CMS) Medicare Provider Analysis and Review (MedPAR) file from fiscal year (FY) 2022 and identified 16,193 renal transplant procedures performed alone without additional organ transplant, and stated of these renal transplants, 948 (5.8%) were repeat transplants. The requestor maintains that currently there is a shortage of donor kidney grafts and any decrease in premature graft failure is beneficial to transplant patients who receive a kidney and those who await a kidney.

[1] Van Loon E, Senev A, Lerut E, et al. Assessing the Complex Causes of Kidney Allograft Loss. Transplantation. 2020 Dec;104(12):2557-2566. DOI: 10.1097/tp.0000000000003192. PMID: 32091487.

Technology
The Kidney Protective Jacket device is a gamma sterilized, portable, encapsulated kidney receptacle, designed to support and thermally insulate a cooled donor kidney during the renal transplantation procedure. The device is made of a biocompatible thermally insulating compound. Both the design and the materials contribute to the insulating effect. According to the requestor, the device is designed to encase the donated kidney under hypothermic aseptic conditions. The device assists in preserving the donor kidney by mitigating heat gain to the donor kidney during transplantation, resulting in reduced temperature rise within the graft. The device is designed to allow the surgeon to grasp and orient the kidney graft during a transplant and prevent egress of the graft from the iliac fossa. Proper surgical orientation allows the surgeon to align the graft with the blood vessels utilized during vascular anastomoses. The device can be used with any surgical approach (e.g., open, laparoscopic, and robotic).

Procedure Description
The kidney transplant procedure occurs in an inpatient hospital facility's operating room. The Kidney Protective Jacket device is delivered to the operating suite within a sterilized, sealed plastic tray. During transplant the device packaging is opened, prepared and secured by the surgeon. On a back bench/table, the surgeon places the Kidney Protective Jacket device around the donor kidney (maintaining the integrity of the renal graft) and secures the kidney receptacle. Ice may be added to receptacle, to augment the deliberate hypothermia. During transplant, the secured/encapsulated donor kidney is placed inside the patient body cavity (in the iliac fossa) for approximately 60 minutes while complex vascular surgical anastomoses are performed. The device can remain in the body cavity for up to three hours.

Per the requestor, the Kidney Protective Jacket is anatomically designed to allow for appropriate donor kidney access during the transplant, without obstructing access to kidney vessels. After the donor kidney undergoes final perfusion (donor graft renal artery and vein are reconstructed with anastomoses to the iliac vessels), the encapsulating device is removed from the donor graft and discarded as medical waste. One Kidney Protective Jacket device is routinely utilized during the procedure. The use of the encapsulated kidney receptacle would be documented in the operative report as a back table/bench preparatory procedure followed by removal. The requestor confirms there have been no complications/sequela/adverse events reported in the use of the Kidney Protective Jacket.

Current Coding: There are no unique ICD-10-PCS codes to describe the use of a protective insulation device on the donor kidney graft during renal transplant. Facilities would report the appropriate code for the kidney transplant procedure performed.

Coding Options

Option 1. Do not create new ICD-10-PCS codes to identify the use of a protective insulation device on the donor kidney graft during renal transplant. Continue coding as listed in current coding.

Option 2. In section 6 table 6A4 Hypothermia of Physiological Systems, create sixth character qualifier value 0 Donor Organ Protective Thermal Insulation and seventh character qualifier value A Intraoperative applied to the body system value 1 Urinary, to identify the use of a protective insulation device on the donor kidney graft during renal transplant.

Section	**6** Extracorporeal or Systemic Therapies		
Body System	**A** Physiological Systems		
Operation	**4** Hypothermia: Extracorporeal lowering of body temperature		
Body System	*Duration*	*Qualifier*	*Qualifier*
Z None	**0** Single **1** Multiple	**Z** No Qualifier	**Z** No Qualifier
ADD 1 Urinary	**0** Single	**ADD 0** Donor Organ Protective Thermal Insulation	**ADD A** Intraoperative

Option 3. In section 8 table 8E0 Other Procedures, create sixth character method value G Donor Organ Protective Thermal Insulation and seventh character qualifier value A Intraoperative applied to the new body region value T Urinary System, to identify the use of a protective insulation device on the donor kidney graft during renal transplant.

Section	**8** Other Procedures		
Body System	**E** Physiological Systems and Anatomical Regions		
Operation	**0** Other Procedures: Methodologies which attempt to remediate or cure a disorder or disease		
Body Region	*Approach*	*Method*	*Qualifier*
ADD T Urinary System	**0** Open	**ADD G** Donor Organ Protective Thermal Insulation	**ADD A** Intraoperative

CMS Recommendation: CMS is seeking input from the audience.

Interim Coding Advice: Continue using current codes as listed in current coding.

Topic # 08 – Insertion of Heterotopic Bicaval Valves into Right Atrium

Issue: There are no unique ICD-10-PCS codes to describe transcatheter insertion of heterotopic bioprosthetic valves into the right atrium. An April 1, 2025 implementation date is being requested.

New Technology Application? No.

Food & Drug Administration (FDA) Approval? No. The TricValve® Transcatheter Bicaval Valve System was granted Breakthrough Device Designation on December 15, 2020 for treatment of severe tricuspid regurgitation. A prospective, multicenter clinical trial of the TricValve® Transcatheter Bicaval Valve System in subjects with severe tricuspid regurgitation (TRICAV) is in process (NCT06137807).

Background: Tricuspid regurgitation (TR) is a condition in which blood flows in the incorrect direction. Referred to as the forgotten valve, TR affects up to 1.6 million patients in the U.S. alone, of whom only 8,000 undergo tricuspid surgery.[1] Severe TR has a > 20% mortality rate[2,3] within 1 year of diagnosis, with < 1% intervention.[4,5] Current treatment options for tricuspid regurgitation include optimal medical therapy (OMT), surgical and transcatheter tricuspid valve repair (TTVr), and transcatheter tricuspid valve replacement (TTVR) therapies.

According to the requestor, the patient cohort for TTVR typically consists of patients with severe TR, leading to symptoms of right heart failure, such as peripheral edema, cardio renal syndrome, and liver congestion, as well as chronic fatigue. The aim of TTVR is to delete the backflow into the organ systems either by targeting the native tricuspid valve (orthotopic device placement) or the backflow itself with prosthetic valves being placed outside the native valve (heterotopic device placement). The TriClip™ Transcatheter Tricuspid Valve Repair (TTVr) System and the EVOQUE Transcatheter Tricuspid Valve Replacement (TTVR) System are *orthotopic* devices (i.e., device is placed in the native tricuspid valve) and are approved in the U.S. for the reduction of tricuspid regurgitation in patients with severe TR inoperable for surgery.

Similarly, per the requestor, the TricValve® System is specifically developed for the treatment of tricuspid regurgitation in patients with severe TR inoperable for surgery, and with the potential to alleviate right heart failure symptoms via reduction in hepatic/abdominal/peripheral venous congestion. The core concept of the device involves implanting mechanisms that isolate the caval veins from the right atrium, thereby effectuating the ventricularization of the right atrium and eliminating backflow to the caval veins. This concept is known as bicaval implantation, and it represents a *heterotopic* (i.e., device placement is outside of the native tricuspid valve) treatment option for tricuspid regurgitation. According to the requestor, the patient cohort for orthotopic (EVOQUE) and heterotopic (TricValve®) replacement is identical, although significantly more patients in an advanced stage can be treated with the TricValve® System. Patients with anatomic considerations such as large coaptation gaps of the tricuspid leaflets or large dilated annuli may not be eligible for orthotopic devices, such as TriClip™ and EVOQUE, while they may be

[1] Taramasso, M. et al Eur Heart J 2017 38(9)
[2] Chorin et al. 2020 Eur Heart J Cardiovasc Imaging 2020 Feb 1;21(2):157-165
[3] Messika-Zeitoun et. al. 2020 Eur J Heart Fail, 2020 Oct;22(10):1803-1813.
[4] Cahill et al. 2021 Heart 2021 May 26;107(12):1003-1009
[5] Fender et al. 2017 JACC. 2017;70(24):2953-2960

eligible for the heterotopic device, TricValve® System.

Technology
The TricValve® Transcatheter Bicaval Valve System is comprised of an intracardiac device consisting of two valve prostheses. The system is indicated for the heterotopic placement of a superior vena cava (SVC) valve prosthesis and an inferior vena cava (IVC) valve prosthesis that extend into the right atrium. Both valve prostheses are supplied pre-mounted on the TricValve® Delivery System. The two valve prostheses for the SVC and IVC have a stent portion and a valve portion. For bicaval implantation to be successful, the backflow to the native caval veins must be eliminated (similar to the reduction of TR with orthotopic devices). This is achieved by implanting/placing both the unidirectional TricValve® valve prostheses into the right atrium. To confirm that the valve prostheses are correctly positioned in the right atrium and ensure complete sealing, they are designed to have long stents that anchor and fix the valves prostheses in the vena cava to provide support and prevent valve displacement.

According to the requestor, the stent portion of the prosthesis for the SVC and IVC allows for adequate fixation and anchoring, while the valve portion of the prosthesis (i.e., leaflets) exerts function and is placed in the right atrium. The valves' functional mechanism (i.e., opening and closing of the leaflets, to prevent regurgitation) operates within the right atrial chamber, like any other transcatheter cardiac bioprosthetic replacement valve.

Procedure Description
The TricValve® implantation procedure is performed by physicians such as interventional cardiologists or cardiac surgeons trained in transcatheter valve procedures. The TricValve® prostheses are pre-assembled into the TricValve® delivery system.

Femoral vein access: The left and right femoral veins are accessed percutaneously. The right femoral vein acts as access for the device. A pigtail catheter is inserted into the left femoral vein for intraprocedural contrast application and pressure measurements.

Prosthetic valve deployment for the SVC: The guidewire is placed into the jugular vein. Subsequently, the valve prosthesis for the SVC (preloaded on the delivery system) is advanced through the femoral vein and inferior vena cava into the right atrium and SVC. The belly of the valve prosthesis is placed over the intersection of the right pulmonary artery with the superior vena cava and its position is confirmed with fluoroscopic and echocardiographic imaging. The valve is partially discharged, and the correct position of the valve is checked by fluoroscopy. The prosthesis is fully retrievable and repositionable.

After the correct position is confirmed, the valve prosthesis is completely deployed adapting to the patient's anatomy as it unfolds. The delivery system is withdrawn, and the insertion capsule is closed. The guidewire remains in place. The correct function of the valve prosthesis is ensured by a pressure measurement.

Prosthesis valve deployment for the IVC: The catheter in the right pulmonary artery is retracted and placed in the hepatic vein inflow to ensure correct positioning. The delivery system and prosthesis are properly hydrated and loaded over the guidewire at the right femoral vein puncture site. The upper part of the stent portion of the prosthesis is positioned at the height of the diaphragm with the skirt of the prosthesis visible just above the hepatic vein inflow. The valve portion of the prosthesis

protrudes fully into the right atrium with the valve sitting inside the right atrium approximately 0.8-1.4 centimeters. The prosthesis is slowly deployed using the delivery system.

Post deployment: Post deployment of both prostheses for the SVC and IVC, correct valve prosthesis function by pressure measurements and optional contrast injection depending on kidney function is performed. All catheters and guidewires are removed, and the access site is closed per hospital protocol. Administration of anticoagulation is administered intraprocedurally.

Current Coding: There are no unique ICD-10-PCS codes to describe transcatheter insertion of heterotopic bioprosthetic valves into the right atrium. Facilities can report the insertion of the valve portion of the bicaval valve prostheses using the existing body part value 6 Atrium, Right, in table 02U, Supplement of Heart and Great Vessels, with device value 8, Zooplastic Tissue, and a percutaneous approach.

Section	**0** Medical and Surgical
Body System	**2** Heart and Great Vessels
Operation	**U** Supplement: Putting in or on biological or synthetic material that physically reinforces and/or augments the function of a portion of a body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Coronary Artery, One Artery **1** Coronary Artery, Two Arteries **2** Coronary Artery, Three Arteries **3** Coronary Artery, Four or More Arteries **5** Atrial Septum **6** Atrium, Right **7** Atrium, Left **9** Chordae Tendineae **A** Heart **D** Papillary Muscle **H** Pulmonary Valve **K** Ventricle, Right **L** Ventricle, Left **M** Ventricular Septum **N** Pericardium **P** Pulmonary Trunk **Q** Pulmonary Artery, Right **R** Pulmonary Artery, Left **S** Pulmonary Vein, Right **T** Pulmonary Vein, Left **V** Superior Vena Cava **W** Thoracic Aorta, Descending **X** Thoracic Aorta, Ascending/Arch	**0** Open **3** Percutaneous 4 Percutaneous Endoscopic	**7** Autologous Tissue Substitute **8** Zooplastic Tissue **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	Z No Qualifier

In addition, facilities should also report existing body part values 0 Inferior Vena Cava and 1 Superior Vena Cava in section X table X2H, Insertion of Cardiovascular System, with device value R Intraluminal Device, Bioprosthetic Valve, to describe insertion of the stent portion of the bicaval valve prostheses.

Section	**X** New Technology
Body System	**2** Cardiovascular System
Operation	**H** Insertion: Putting in a nonbiological appliance that monitors, assists, performs, or prevents a physiological function but does not physically take the place of a body part

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
0 Inferior Vena Cava **1** Superior Vena Cava	**3** Percutaneous	**R** Intraluminal Device, Bioprosthetic Valve	**9** New Technology Group 9

Coding Options

Option 1. Do not create new ICD-10-PCS codes to identify the transcatheter insertion of a heterotopic bioprosthetic valve in the right atrium. Continue coding as listed in current coding.

Option 2. In section X table X2U, Supplement of Cardiovascular System, create new device value Y Intraluminal Device, Heterotopic Bioprosthetic Valve(s), applied to the body part value 9 Atrium, Right, to identify the transcatheter insertion of a heterotopic bioprosthetic valve in the right atrium. Continue to report the codes from section X table X2H, Insertion of Cardiovascular System, with device value R Intraluminal Device, Bioprosthetic Valve, to describe insertion of the stent portion of the bicaval valve prostheses.

Section	**X** New Technology
Body System	**2** Cardiovascular System
Operation	**U** Supplement: Putting in or on biological or synthetic material that physically reinforces and/or augments the function of a portion of a body part

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
4 Coronary Arteries/Artery	**0** Open	**7** Vein Graft Extraluminal Support Device(s)	**9** New Technology Group 9
Q Upper Extremity Vein, Right **R** Upper Extremity Vein, Left	**0** Open	**P** Synthetic Substitute, Extraluminal Support Device	**9** New Technology Group 9
ADD 9 Atrium, Right	**3** Percutaneous	**ADD Y** Intraluminal Device, Heterotopic Bioprosthetic Valve(s)	**A** New Technology Group 10

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.

Topic # 09 - Section X Update
September 2024 ICD-10 Coordination and Maintenance Committee Meeting

For this September 2024 meeting we are sharing our analysis results for the Group 6 section X codes from FY 2021, 2022, and 2023. At the March 2025 meeting we will share an updated analysis to include the results for the Group 6 section X codes for FY 2024, along with the CMS recommendation.

For the proposed disposition of a section X code(s), we consider the following during our review:

- Was the procedure code related to a new technology add-on payment application (NTAP)?
- If yes, was the technology approved for the NTAP?
- What is the frequency (total number of cases) of this procedure code as reported in the Medicare Provider Analysis and Review (MedPAR) data for the relevant FYs?
- Based on review of the data and the clinical aspects of each procedure code, we will propose one of the options below. Updates are shown as underlined below.
    1. Leave the code in section X (e.g., procedure codes related to the administration of a specific medication)
    2. Delete the section X code. Revise Index and/or Reference key entries to direct the user to an existing code in the Medical and Surgical or other section of ICD-10-PCS (e.g., NTAP has expired, data analysis and clinical review justifies incorporating this technology/procedure into the main Medical and Surgical section)
    3. Delete the section X code, corresponding Index entries, and any Reference Key entries from the classification (e.g., the procedure is not reported as anticipated in the data, therefore the absence of a unique code for this technology/procedure in the classification has minimal impact)
    4. Create a new code(s) in Med/Surg or other section of ICD-10-PCS and delete the code from section X. (e.g., NTAP has expired, data analysis and clinical review justifies uniquely identifying the technology in the Medical and Surgical section). The corresponding Index entries for the section X code(s) will also be deleted and new Index entries, along with any Reference Key entries will be created to reflect the newly established code(s).

Section X – September 2024 Update
Group 6

ICD-10-PCS Code	Code Description	FY 2021		FY 2022		FY 2023		FY 2024				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
X2AH336	Cerebral embolic filtration, extracorporeal flow reversal circuit from right common carotid artery, percutaneous approach, new technology group 6	854	NO	856	NO	2530	NO		NO	4240	TBA at March meeting	Enroute® NPS (Neuroprotection System)
X2AJ336	Cerebral embolic filtration, extracorporeal flow reversal circuit from left common carotid artery, percutaneous approach, new technology group 6	821	NO	821	NO	2468	NO		NO	4110	TBA at March meeting	Enroute® NPS (Neuroprotection System)
XNU0356	Supplement lumbar vertebra with mechanically expandable (paired) synthetic substitute, percutaneous approach, new technology group 6	199	YES	200	YES	344	NO		NO	743	TBA at March meeting	SpineJack® Expansion Kit
XNU4356	Supplement thoracic vertebra with mechanically expandable (paired) synthetic substitute, percutaneous approach, new technology group 6	155	YES	158	YES	227	NO		NO	540	TBA at March meeting	SpineJack® Expansion Kit
XW013G6	Introduction of REGN-COV2 monoclonal antibody into subcutaneous tissue, percutaneous approach, new technology group 6	0	NO	0	NO	0	NO		NO	0	TBA at March meeting	Casirivimab (REGN10933) and Imdevimab (REGN10987)
XW013H6	Introduction of other new technology monoclonal antibody into subcutaneous tissue, percutaneous approach, new technology group 6	6	NO	6	NO	10	NO		NO	22	TBA at March meeting	
XW013K6	Introduction of leronlimab monoclonal antibody into subcutaneous tissue, percutaneous approach, new technology group 6	17	NO	19	NO	0	NO		NO	36	TBA at March meeting	
XW013S6	Introduction of COVID-19 vaccine dose 1 into subcutaneous tissue,	102	NO	102	NO	11	NO		NO	215	TBA at March meeting	COMIRNATY® SPIKEVAX®

ICD-10-PCS Code	Code Description	FY 2021		FY 2022		FY 2023		FY 2024				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
	percutaneous approach, new technology group 6											
XW013T6	Introduction of COVID-19 vaccine dose 2 into subcutaneous tissue, percutaneous approach, new technology group 6	28	NO	28	NO	1	NO		NO	57	TBA at March meeting	COMIRNATY® SPIKEVAX®
XW013U6	Introduction of COVID-19 vaccine into subcutaneous tissue, percutaneous approach, new technology group 6	46	NO	46	NO	13	NO		NO	105	TBA at March meeting	COMIRNATY® SPIKEVAX®
XW023S6	Introduction of COVID-19 vaccine dose 1 into muscle, percutaneous approach, new technology group 6	2505	NO	2507	NO	321	NO		NO	5333	TBA at March meeting	COMIRNATY® SPIKEVAX®
XW023T6	Introduction of COVID-19 vaccine dose 2 into muscle, percutaneous approach, new technology group 6	799	NO	800	NO	99	NO		NO	1698	TBA at March meeting	COMIRNATY® SPIKEVAX®
XW023U6	Introduction of COVID-19 vaccine into muscle, percutaneous approach, new technology group 6	2336	NO	2339	NO	575	NO		NO	5250	TBA at March meeting	COMIRNATY® SPIKEVAX®
XW03306	Introduction of brexanolone into peripheral vein, percutaneous approach, new technology group 6	1	NO	1	NO	5	NO		NO	7	TBA at March meeting	ZULRESSO™
XW03326	Introduction of nerinitide into peripheral vein, percutaneous approach, new technology group 6	2	NO	2	NO	0	NO		NO	4	TBA at March meeting	
XW03336	Introduction of durvalumab antineoplastic into peripheral vein, percutaneous approach, new technology group 6	23	YES	23	YES	25	NO		NO	71	TBA at March meeting	IMFINZI®
XW03366	Introduction of lefamulin anti-infective into peripheral vein, percutaneous approach, new technology group 6	3	YES	3	YES	2	NO		NO	8	TBA at March meeting	XENLETA®

ICD-10-PCS Code	Code Description	FY 2021		FY 2022		FY 2023		FY 2024				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
XW03396	Introduction of ceftolozane/tazobactam anti-infective into peripheral vein, percutaneous approach, new technology group 6	416	YES	499	YES	1458	NO		NO	2373	TBA at March meeting	ZERBAXA®
XW033A6	Introduction of cefiderocol anti-infective into peripheral vein, percutaneous approach, new technology group 6	106	YES	144	YES	501	YES (HABP/ VABP only[1])		NO	751	TBA at March meeting	FETROJA®
XW033B6	Introduction of omadacycline anti-infective into peripheral vein, percutaneous approach, new technology group 6	5	YES	5	YES	18	NO		NO	28	TBA at March meeting	NUZYRA™
XW033C6	Introduction of eculizumab into peripheral vein, percutaneous approach, new technology group 6	89	YES	91	YES	100	NO		NO	280	TBA at March meeting	Soliris®
XW033D6	Introduction of atezolizumab antineoplastic into peripheral vein, percutaneous approach, new technology group 6	67	YES	70	YES	48	NO		NO	185	TBA at March meeting	TECENTRIQ®
XW033E6	Introduction of etesevimab monoclonal antibody into peripheral vein, percutaneous approach, new technology group 6	131	NO	131	NO	6	NO		NO	268	TBA at March meeting	
XW033F6	Introduction of bamlanivimab monoclonal antibody into peripheral vein, percutaneous approach, new technology group 6	1289	NO	1291	NO	40	NO		NO	2680	TBA at March meeting	
XW033G6	Introduction of REGN-COV2 monoclonal antibody into peripheral vein, percutaneous approach, new technology group 6	1240	NO	1242	NO	7	NO		NO	2489	TBA at March meeting	Casirivimab (REGN10933) and Imdevimab (REGN10987)

[1] HABP/VABP – Approved for the treatment of hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) only.

ICD-10-PCS Code	Code Description	FY 2021		FY 2022		FY 2023		FY 2024				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
XW033H6	Introduction of other new technology monoclonal antibody into peripheral vein, percutaneous approach, new technology group 6	485	NO	485	NO	892	NO		NO	1862	TBA at March meeting	
XW033L6	Introduction of CD24Fc immunomodulator into peripheral vein, percutaneous approach, new technology group 6	0	NO	0	NO	1	NO		NO	1	TBA at March meeting	
XW04306	Introduction of brexanolone into central vein, percutaneous approach, new technology group 6	0	NO	0	NO	1	NO		NO	1	TBA at March meeting	ZULRESSO™
XW04326	Introduction of nerinitide into central vein, percutaneous approach, new technology group 6	1	NO	1	NO	0	NO		NO	2	TBA at March meeting	
XW04336	Introduction of durvalumab antineoplastic into central vein, percutaneous approach, new technology group 6	6	YES	6	YES	11	NO		NO	23	TBA at March meeting	IMFINZI®
XW04366	Introduction of lefamulin anti-infective into central vein, percutaneous approach, new technology group 6	2	YES	2	YES	0	NO		NO	4	TBA at March meeting	XENLETA®
XW04396	Introduction of ceftolozane/tazobactam anti-infective into central vein, percutaneous approach, new technology group 6	66	YES	66	YES	281	NO		NO	413	TBA at March meeting	ZERBAXA®
XW043A6	Introduction of cefiderocol anti-infective into central vein, percutaneous approach, new technology group 6	27	YES	42	YES	87	YES (HABP/ VABP only)		NO	156	TBA at March meeting	FETROJA®
XW043B6	Introduction of omadacycline anti-infective into central vein, percutaneous approach, new technology group 6	2	YES	2	YES	6	NO		NO	10	TBA at March meeting	NUZYRA™

ICD-10-PCS Code	Code Description	FY 2021		FY 2022		FY 2023		FY 2024				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
XW043C6	Introduction of eculizumab into central vein, percutaneous approach, new technology group 6	33	YES	33	YES	31	NO		NO	97	TBA at March meeting	Soliris®
XW043D6	Introduction of atezolizumab antineoplastic into central vein, percutaneous approach, new technology group 6	46	NO	46	NO	0	NO		NO	92	TBA at March meeting	TECENTRIQ®
XW043E6	Introduction of etesevimab monoclonal antibody into central vein, percutaneous approach, new technology group 6	4	NO	4	NO	0	NO		NO	8	TBA at March meeting	
XW043F6	Introduction of bamlanivimab monoclonal antibody into central vein, percutaneous approach, new technology group 6	20	NO	20	NO	1	NO		NO	41	TBA at March meeting	
XW043G6	Introduction of REGN-COV2 monoclonal antibody into central vein, percutaneous approach, new technology group 6	23	NO	23	NO	0	NO		NO	46	TBA at March meeting	Casirivimab (REGN10933) and Imdevimab (REGN10987)
XW043H6	Introduction of other new technology monoclonal antibody into central vein, percutaneous approach, new technology group 6	19	NO	19	NO	20	NO		NO	58	TBA at March meeting	
XW043L6	Introduction of CD24Fc immunomodulator into central vein, percutaneous approach, new technology group 6	1	NO	1	NO	0	NO		NO	2	TBA at March meeting	
XW0DX66	Introduction of lefamulin anti-infective into mouth and pharynx, external approach, new technology group 6	0	YES	0	YES	1	NO		NO	1	TBA at March meeting	XENLETA®
XW0DXM6	Introduction of baricitinib into mouth and pharynx, external approach, new technology group 6	4,547	NO	4676	NCTAP [2]	3088	NCTAP		NO	12311	TBA at March meeting	Olumiant®

[2] NCTAP – New COVID-19 Treatments Add-on Payment. Through NCTAP, Medicare provides an enhanced payment from November 2, 2020 through September 30, 2023, for eligible inpatient cases that use certain new products with current FDA approval or emergency use authorization (EUA) to treat COVID-19.

ICD-10-PCS Code	Code Description	FY 2021		FY 2022		FY 2023		FY 2024				
		Freq	NTAP	Freq	NTAP	Freq	NTAP	Freq	NTAP	Total Freq	CMS Recommendation	Technology Brand Name
XW0G7M6	Introduction of baricitinib into upper GI, via natural or artificial opening, new technology group 6	164	NO	164	NCTAP	97	NCTAP		NO	425	TBA at March meeting	Olumiant®
XW0G886	Introduction of mineral-based topical hemostatic agent into upper GI, via natural or artificial opening endoscopic, new technology group 6	1,741	YES	1806	YES	2936	NO		NO	6483	TBA at March meeting	Hemospray® Endoscopic Hemostat
XW0H7M6	Introduction of baricitinib into lower GI, via natural or artificial opening, new technology group 6	17	NO	17	NCTAP	7	NCTAP		NO	41	TBA at March meeting	Olumiant®
XW0H886	Introduction of mineral-based topical hemostatic agent into lower GI, via natural or artificial opening endoscopic, new technology group 6	271	YES	276	YES	413	NO		NO	960	TBA at March meeting	Hemospray® Endoscopic Hemostat
XW0Q316	Introduction of eladocagene exuparvovec into cranial cavity and brain, percutaneous approach, new technology group 6	1	NO	1	NO	0	NO		NO	2	TBA at March meeting	Upstaza™
XXE5XN6	Measurement of infection, positive blood culture fluorescence hybridization for organism identification, concentration and susceptibility, new technology group 6	0	NO	0	NO	1	NO		NO	1	TBA at March meeting	Accelerate PhenoTest™ BC kit
XXEBXQ6	Measurement of infection, lower respiratory fluid nucleic acid-base microbial detection, new technology group 6	368	NO	399	NO	2318	NO		NO	3085	TBA at March meeting	The BioFire Pneumonia Panel

Topic # 10 - ICD-10-PCS Index Addenda*

Lttr A
Main Add Aortic root use Thoracic Aorta, Ascending/Arch

Lttr G
Main Add GORE(R) ACUSEAL Vascular Graft use Synthetic Substitute
Main Add GORE(R) CARDIOFORM Septal Occluder use Synthetic Substitute
Main Add GORE(R) PROPATEN(R) Vascular Graft use Synthetic Substitute
Main Add GORE(R) VIABAHN(R) Endoprosthesis use Intraluminal Device
Main Add GORE(R) VIABIL(R) Biliary Endoprosthesis use Intraluminal Device
Main Add GORE(R) VIATORR(R) TIPS Endoprosthesis use Synthetic Substitute

Lttr T
Main Add Transjugular Intrahepatic Portosystemic Shunt (TIPS)
see Lower Veins, Bypass, Portal Vein 0618

Lttr Z
Main Add ZEVTERA(tm) use Ceftobiprole Medocaril Anti-infective

ICD-10-PCS Body Part Key Addenda

Section 0 Medical and Surgical
Axis 4 Body Part
Term Thoracic Aorta, Ascending/Arch
Includes Add Aortic root

ICD-10-PCS Substance Key Addenda

Section X New Technology
Axis 6 Device / Substance / Technology
Row Add
Term Add Ceftobiprole Medocaril Anti-infective
Includes Add ZEVTERA(tm)

ICD-10-PCS Table Addenda

Medical and Surgical Section

Axis 3 Root Operation
Larynx Transplant

Source	Description	Code specification
2024, CMS internal review	In the Medical and Surgical section, add root operation Y Transplantation to body system C Mouth and Throat, applied to the body part value S Larynx, approach value 0 Open and qualifier values 0 Allogeneic and 1 Syngeneic.	Add: 0CYS0Z[01] (2 codes)

**All proposed addenda updates are being considered for implementation on April 1, 2025.*

	This proposed change would enable the capture of procedures such as laryngeal transplantation. The third-documented larynx transplant in the United States was performed in 2024. Larynx transplant is a promising option to restore quality-of-life in people with severe laryngeal dysfunction or a laryngectomy.	

EXAMPLE

Section	**0** Medical and Surgical
Body System	**C** Mouth and Throat
Operation	**ADD Y** Transplantation: Putting in or on all or a portion of a living body part taken from another individual or animal to physically take the place and/or function of all or a portion of a similar body part

Body Part	*Approach*	*Device*	*Qualifier*
ADD S Larynx	**ADD 0** Open	**ADD Z** No Device	**ADD 0** Allogeneic **ADD 1** Syngeneic

Axis 4 Body Part
Fusion of Coccygeal Joint

Source	Description	Code specification
2024, CMS internal review	In the Medical and Surgical section table 0SG, Fusion of Lower Joints, delete body part value 6 Coccygeal Joint, for all device values and all approaches. This proposed deletion would remove clinically invalid codes that describe fusion of the coccygeal joint. The coccyx (tailbone) is the terminal part of the vertebral column, comprised of three to five (usually four) vertebrae fused together to make a single sphenoid bone. Fusion of the coccyx begins at age 20 and is usually completed by age 30. Some articulation is possible between coccygeal vertebrae until they are fused, but they do not move very much. The operative treatment for idiopathic coccydynia (coccygodynia), or coccydynia caused by conditions such as fractures, dislocations, sprains, and teratomas, is complete or partial removal of the coccyx (coccygectomy), not surgical fusion of a coccygeal joint.	Delete: 0SG6[034][47JK]Z (12 codes)

EXAMPLE

Section	**0** Medical and Surgical
Body System	**S** Lower Joints
Operation	**G** Fusion: Joining together portions of an articular body part rendering the articular body part immobile

Body Part	*Approach*	*Device*	*Qualifier*
5 Sacrococcygeal Joint **DELETE 6** Coccygeal Joint **7** Sacroiliac Joint, Right **8** Sacroiliac Joint, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic	**4** Internal Fixation Device **7** Autologous Tissue Substitute **J** Synthetic Substitute **K** Nonautologous Tissue Substitute	**Z** No Qualifier

Axis 5 Approach
Cardiac Stereotactic Body Radiotherapy (SBRT)

Source	**Description**	**Code specification**
2024, Coding Clinic Editorial Advisory Board & CMS internal review	In the Medical and Surgical section table 025, Destruction of Heart and Great Vessels, add the approach value X External, applied to the body part value 8 Conduction Mechanism and qualifier value Z No Qualifier. This proposed change would enable the capture of procedures such as cardiac stereotactic body radiotherapy (SBRT). Cardiac SBRT, also called cardiac radio-ablation, is a non-invasive procedure to treat ventricular tachycardia (VT) that allows for the precise delivery of high-dose radiation to target tissue to any desired area within the body, including those that may be inaccessible in traditional catheter ablation, while minimizing radiation exposure to adjacent anatomic structures.	Add: 0258XZZ (1 code)

EXAMPLE

Section	**0** Medical and Surgical
Body System	**2** Heart and Great Vessels
Operation	**5** Destruction: Physical eradication of all or a portion of a body part by the direct use of energy, force, or a destructive agent

Body Part	*Approach*	*Device*	*Qualifier*
8 Conduction Mechanism	**0** Open 4 Percutaneous Endoscopic **ADD X** External	**Z** No Device	**Z** No Qualifier
8 Conduction Mechanism	**3** Percutaneous	**Z** No Device	**F** Irreversible Electroporation **Z** No Qualifier

Endoscopic Tracheoesophageal Puncture

Source	Description	Code specification
2024, Coding Clinic Editorial Advisory Board & CMS internal review	In the Medical and Surgical section table 0B1, Bypass of Respiratory System, add the approach value 8 Via Natural or Artificial Opening Endoscopic, applied to the body part value 1 Trachea, device value D Intraluminal Device and qualifier value 6 Esophagus. This proposed change would enable the capture of procedures such as endoscopic tracheoesophageal puncture (TEP). TEP creates a path for air to move from the lungs to the esophagus to restore voice and speech communication following a total laryngectomy. During the TEP procedure, a surgeon creates a small hole about the size of a pencil eraser in the wall between the trachea and the esophagus. A small one-way valve, called a tracheoesophageal voice prosthesis, is placed inside the hole to direct air into the throat.	Add: 0B118D6 (1 code)

EXAMPLE

Section	**0** Medical and Surgical
Body System	**B** Respiratory System
Operation	**1** Bypass: Altering the route of passage of the contents of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
1 Trachea	**0** Open **ADD 8** Via Natural or Artificial Opening Endoscopic	**D** Intraluminal Device	**6** Esophagus
1 Trachea	**0** Open	**F** Tracheostomy Device **Z** No Device	**4** Cutaneous
1 Trachea	**3** Percutaneous **4** Percutaneous Endoscopic	**F** Tracheostomy Device **Z** No Device	**4** Cutaneous

Index entries to accompany this addenda proposal:

ICD-10-PCS Index Addenda

Lttr F
Main Delete Fistulization, Tracheoesophageal 0B110D6
Main Add Fistulization, Tracheoesophageal 0B11

Lttr T
Main Delete Tracheoesophageal fistulization 0B110D6
Main Add Tracheoesophageal fistulization 0B11

Main Delete Tracheoesophageal Puncture (TEP) 0B110D6
Main Add Tracheoesophageal Puncture (TEP) 0B11

Axis 6 Device
Cricothyrotomy

Source	Description	Code specification
2024, Coding Clinic Editorial Advisory Board & CMS internal review	In the Medical and Surgical section table 0B1, Bypass of Respiratory System, add the device value H Other Airway Device, applied to the body part value 1 Trachea, approach values 0 Open and 3 Percutaneous, with qualifier value 4 Cutaneous. This proposed change would enable the capture of procedures such as cricothyrotomy. Cricothyrotomy (also called cricothyroidotomy) is a rarely performed but potentially life-saving procedure of last resort that involves placement of a tube through an incision in the cricothyroid membrane to establish an airway for oxygenation and ventilation when endotracheal (ET) intubation is contraindicated or unachievable, and more routine methods (e.g., laryngeal mask airway) fail to adequately ventilate and oxygenate the patient. Clinicians use cricothyrotomy in emergency situations where securing an airway quickly is paramount. In contrast, tracheostomy is a more stable long-term solution for airway management, allowing for comfort and more straightforward airway clearance. Although both procedures aim to provide airway access, they differ significantly in technique, intended indications, and duration of use. There are three main approaches to cricothyroidotomy: open cricothyrotomy, needle cricothyrotomy, and percutaneous cricothyrotomy using the Seldinger technique.[1] In the "traditional" (open) cricothyrotomy technique, a 2- to 3-cm vertical incision is made through the skin and subcutaneous tissue. The cricothyroid membrane is then palpated through the incision and a horizontal incision of less than 1.0 cm in length is made through the cricothyroid membrane into the trachea and a tracheostomy tube is placed through the incision to establish an airway. If a tracheostomy tube is not available or if there is difficulty placing the tracheostomy tube into the opening in the cricothyroid membrane, a 6-0 cuffed ET tube cut to a shorter length can be placed as an alternative to a tracheostomy tube. There are no absolute contraindications to open cricothyrotomy in adults, but it should not be performed in children <10 years old. Needle cricothyrotomy, a temporary method that uses a 12- to 14-gauge angiocatheter attached to a bag-valve-mask device (or a jet ventilator if available), is the preferred cricothyrotomy method for children <10 years old.	Add: 0B11[03]H4 (2 codes)

[1] McKenna P, Desai NM, Tariq A, et al. Cricothyrotomy. [Updated 2023 Feb 4]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK537350/

	After cricothyrotomy, a permanent tracheostomy should be placed within 24 hours. Needle cricothyrotomy can be used for approximately 40 minutes, after which time carbon dioxide accumulates which can be particularly devastating in patients with head trauma.[2,3]	

EXAMPLE

Section	**0** Medical and Surgical
Body System	**B** Respiratory System
Operation	**1** Bypass: Altering the route of passage of the contents of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
1 Trachea	**0** Open	**D** Intraluminal Device	**6** Esophagus
1 Trachea	**0** Open **3** Percutaneous	**F** Tracheostomy Device **ADD H** Other Airway Device **Z** No Device	**4** Cutaneous
1 Trachea	**4** Percutaneous Endoscopic	**F** Tracheostomy Device **Z** No Device	**4** Cutaneous

Index entries to accompany this addenda proposal:

ICD-10-PCS Index Addenda

Lttr C

Main Add Cricothyroidotomy 0B11

Main Add Cricothyrotomy 0B11

Axis 7 Qualifier

Vaginal Reconstruction Using Ileum

Source	**Description**	**Code specification**
2024, public request with CMS internal review	In the Medical and Surgical section table 0DX, Transfer of Gastrointestinal System, add qualifier value 7 Vagina, applied to the body part value 8 Small Intestine and to the approach values 0 Open and 4 Percutaneous Endoscopic. This proposed change would enable the capture of detail for procedures such as ileal interposition vaginoplasty, where an isolated segment of ileum (small intestine) is pedicled on an artery to maintain the blood supply and transferred to the vagina for reconstructive treatment of various anomalies (e.g., cloacal anomaly, cloacal exstrophy or vaginal agenesis).	Add: 0DX8[04]Z7 (2 codes)

[2] Roberts, J. R., & Hedges, J. R. (1998). Clinical procedures in emergency medicine. WB Saunders Company.

[3] Ali J (2014). Priorities in multisystem trauma. Hall J.B., & Schmidt G.A., & Kress J.P.(Eds.), Principles of Critical Care, 4e. McGraw-Hill Education. https://accessmedicine.mhmedical.com/content.aspx?bookid=1340&sectionid=80026930

EXAMPLE

Section	**0** Medical and Surgical
Body System	**D** Gastrointestinal System
Operation	**X** Transfer: Moving, without taking out, all or a portion of a body part to another location to take over the function of all or a portion of a body part

Body Part	*Approach*	*Device*	*Qualifier*
6 Stomach	**0** Open **4** Percutaneous Endoscopic	**Z** No Device	**5** Esophagus
8 Small Intestine	**0** Open **4** Percutaneous Endoscopic	**Z** No Device	**5** Esophagus **ADD 7** Vagina **B** Bladder **C** Ureter, Right **D** Ureter, Left **F** Ureters, Bilateral
E Large Intestine	**0** Open **4** Percutaneous Endoscopic	**Z** No Device	**5** Esophagus **7** Vagina **B** Bladder
U Omentum	**0** Open **4** Percutaneous Endoscopic	**Z** No Device	**V** Thoracic Region **W** Abdominal Region **X** Pelvic Region **Y** Inguinal Region

Resection of a Transplanted Kidney

Source	Description	Code specification
2024, Coding Clinic Editorial Advisory Board & CMS internal review	In the Medical and Surgical section table 0TT, Resection of Urinary System, add qualifier values 0 Allogeneic, 1 Syngeneic, and 2 Zooplastic, applied to the body part values 0 Kidney, Right, and 1 Kidney, Left, and to the approach value 0 Open. In circumstances where documentation indicates that the resected transplanted kidney was centrally located, the appropriate body part value (e.g. right or left kidney) is assigned based on the location of the vascular anastomosis. This proposed change would enable the capture of detail for procedures such as the surgical removal of a transplanted kidney, also known as renal transplantectomy, or transplant nephrectomy. Better tracking of transplant nephrectomy is important for studying the outcomes of surgery and providing evidence to guide appropriate care.	Add: 0TT[01]0Z[012] (6 codes)

EXAMPLE

Section	**0** Medical and Surgical
Body System	**T** Urinary System
Operation	**T** Resection: Cutting out or off, without replacement, all of a body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Kidney, Right **1** Kidney, Left	**0** Open	**Z** No Device	**ADD 0** Allogeneic **ADD 1** Syngeneic **ADD 2** Zooplastic **Z** No Qualifier
2 Kidneys, Bilateral	**0** Open	**Z** No Device	**Z** No Qualifier
0 Kidney, Right **1** Kidney, Left	**4** Percutaneous Endoscopic	**Z** No Device	**G** Hand-Assisted **Z** No Qualifier

2 Kidneys, Bilateral			
3 Kidney Pelvis, Right **4** Kidney Pelvis, Left **6** Ureter, Right **7** Ureter, Left **B** Bladder **C** Bladder Neck **D** Urethra	**0** Open **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**Z** No Device	**Z** No Qualifier

Mechanical Cervical Ripening in Labor Induction

Source	Description	Code specification
2024, Coding Clinic Editorial Advisory Board & CMS internal review	In the Medical and Surgical section table 0U7, Dilation of Female Reproductive System, add qualifier value J Temporary applied to the body part value C Cervix, and to the approach value 7 Via Natural or Artificial Opening. This proposed change would enable the capture of more accurate detail for procedures such as the use of balloon catheters or hygroscopic osmotic dilators (e.g., Laminaria, Dilapan-S® rods) to dilate the cervix. Once placed, these mechanical dilators remain in place from a few hours to a maximum of 24 hours, depending on the method and indication, and are not meant to be left in place after delivery.	Add: 0U7C7DJ (1 code)

EXAMPLE

Section	**0** Medical and Surgical		
Body System	**U** Female Reproductive System		
Operation	**7** Dilation: Expansion an orifice or the lumen of a tubular body part		
Body Part	*Approach*	*Device*	*Qualifier*
5 Fallopian Tube, Right **6** Fallopian Tube, Left **7** Fallopian Tubes, Bilateral **9** Uterus **G** Vagina	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**D** Intraluminal Device **Z** No Device	**Z** No Qualifier
C Cervix	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**D** Intraluminal Device **Z** No Device	**Z** No Qualifier
C Cervix	**7** Via Natural or Artificial Opening	**D** Intraluminal Device	**ADD J** Temporary
K Hymen	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic **X** External	**D** Intraluminal Device **Z** No Device	**Z** No Qualifier

Obstetrics Section
Axis 5 Approach

Open Extraction of Retained Products of Conception

Source	Description	Code specification
2024, public comment & CMS internal review	In the Obstetrics section table 10D, Extraction of Products of Conception, add approach value 0 Open, applied to the body part value 1 Products of Conception, Retained, to identify the removal of retained products of conception (RPOC) using an open approach. This proposed change would enable the capture of detail for procedures such as the extraction of RPOC following cesarean delivery, performed by reopening the incision site, when the RPOC cannot be successfully extracted through the vagina and a return to the operating room is required.	Add: 10D10ZZ (1 code)

EXAMPLE

Section	**1** Obstetrics
Body System	**0** Pregnancy
Operation	**D** Extraction: Pulling or stripping out or off all or a portion of a body part by the use of force

Body Part	*Approach*	*Device*	*Qualifier*
1 Products of Conception, Retained	**7** Via Natural or Artificial Opening **8** Via Natural or Artificial Opening Endoscopic	**Z** No Device	**9** Manual **Z** No Qualifier
1 Products of Conception, Retained	**ADD 0** Open	**Z** No Device	**Z** No Qualifier

Administration Section
Axis 7 Qualifier

Introduction of Other Substances in Joints

Source	Description	Code specification
2024, CMS internal review	In the Administration section table 3E0 Introduction , add the qualifier value C Other Substance applied to body region value U Joints, to capture procedures such as the utilization of bone graft material in open ankle joint fusions.	Add: 3E0U0GC (1 code)

EXAMPLE

Section	**3** Administration
Body System	**E** Physiological Systems and Anatomical Regions
Operation	**0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products

Body System / Region	*Approach*	*Substance*	*Qualifier*
U Joints	**0** Open	**2** Anti-infective	**8** Oxazolidinones **9** Other Anti-infective
U Joints	**0** Open	**G** Other Therapeutic Substance	**B** Recombinant Bone Morphogenetic Protein **ADD C** Other Substance

Other Procedures Section
Axis 7 Qualifier

Negative Pressure Wound Therapy

Source	Description	Code specification
2024, Coding Clinic Editorial Advisory Board & CMS internal review	In Other Procedures section table 8E0, add the qualifier value P Negative Pressure Therapy, applied to body region value H Integumentary System and Breast, approach value X External, and method value Y Other Method to capture procedures such as the utilization of negative pressure therapy in the adjunctive management of acute and chronic wounds. Negative pressure wound therapy (NPWT) aims to treat complex wounds which are non-healing or at risk of non-healing, such as diabetic foot ulcers or skin grafts. Also known as vacuum-assisted wound closure (VAC), NPWT includes the placement of a dressing (foam or gauze) directly on the wound and an adhesive film that covers and seals the dressing and wound. A drainage tube leads from under the adhesive film and connects to a portable vacuum pump. The vacuum pump removes air pressure over the wound by applying gentle controlled suction to pull wound debris into a collection chamber, along with any fluids that drain from the wound. It may do this constantly, or in cycles, and the dressing is changed every 24 to 72 hours. In recent years, the use of negative pressure wound therapy with instillation and dwell time (NPWTi-d) has gained wider adoption and interest due in part to the increasing complexity of wounds and patient conditions. In NPWTi-d, a predetermined volume of topical wound solution is instilled and allowed to dwell in the wound bed at set intervals for a user-selected period of time before NPWT is resumed to help promote wound healing in certain complex wounds.	Add: 8E0HXYP (1 code)

EXAMPLE

Section	**8** Other Procedures
Body System	**E** Physiological Systems and Anatomical Regions
Operation	**0** Other Procedures: Methodologies which attempt to remediate or cure a disorder or disease

Body Region	*Approach*	*Method*	*Qualifier*
H Integumentary System and Breast	**3** Percutaneous	**0** Acupuncture	**0** Anesthesia **Z** No Qualifier
H Integumentary System and Breast	**X** External	**6** Collection	**2** Breast Milk
H Integumentary System and Breast	**X** External	**Y** Other Method	**9** Piercing **ADD P** Negative Pressure Therapy

New Technology Section
Axis 6 Device / Substance / Technology

OTL-200 Name Revised

Source	Description	Code specification
2024, public request with CMS internal review	In New Technology section table XW1 Transfusion, revise the axis 6 device/substance/technology value G from OTL-200 to Atidarsagene Autotemcel. This change request is from the manufacturer and reflects the final name of the drug. LENMELDY™ (atidarsagene autotemcel), formerly known as OTL-200 and marketed in Europe as Libmeldy®, is a gene therapy consisting of autologous CD34+ cells containing hematopoietic stem cells (HSCs), transduced with a lentiviral vector (LVV) encoding the human arylsulfatase A (ARSA) gene, suspended in cryopreservation solution. LENMELDY™ is intended for one-time administration to add functional copies of the ARSA gene for the treatment of children with pre-symptomatic late infantile (PSLI), pre-symptomatic early juvenile, (PSEJ), or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD).	Revise: XW1[34]3G8 (2 codes)

EXAMPLE

Section	**X** New Technology		
Body System	**W** Anatomical Regions		
Operation	**1** Transfusion: Putting in blood or blood products		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**F** OTL-103 **REVISE from G** OTL-200 **REVISE to G** Atidarsagene Autotemcel	**8** New Technology Group 8

Index entries to accompany this addenda proposal:

ICD-10-PCS Index Addenda

Lttr A
Main Add Atidarsagene autotemcel XW1

Lttr L
Main Add LENMELDY(tm) use Atidarsagene Autotemcel

Lttr O
Main Delete OTL-200 XW1

Lttr N
Main New Technology
Delete OTL-200 XW1
Add Atidarsagene Autotemcel XW1

Substance Key entries to accompany this addenda proposal:

ICD-10-PCS Substance Key Addenda

Section X New Technology

Axis 6		Device / Substance / Technology
Term	Add	Atidarsagene Autotemcel
Includes	Add	LENMELDY(tm)

MS-DRG Classifications and Software

Notice Regarding Upcoming Releases of the MS-DRG Grouper and Medicare Code Editor (MCE)

The current versions of the MS-DRG Grouper and MCE use Java software and are currently based on Java version 8. Support for Java version 8 will end by November 2026. Hospitals and their software vendors who implement these programs in a mainframe environment will be impacted by this change. CMS is preparing now to convert the programs to Java version 17.

For the upcoming year, the Fiscal Year 2025 releases of these programs, effective October 2024, will include two Common Business-Oriented Language (COBOL) Java bridge modules instead of the one that is currently delivered. CMS will continue to provide the existing bridge module that utilizes the 31-bit, Java 8 Java Virtual Machine (JVM) environment. We will also provide a new bridge module that will utilize the 64-bit, Java 17 JVM. The Java jar file for each will continue to be compiled using Java 8. This will preserve backwards compatibility with all existing mainframe deployments (both batch and Customer Information Control System (CICS)). The installation guides for the programs will provide notice of the changes. This will allow users to test upgrades to their systems over the next year to prepare to move to Java 17.

The release of the Fiscal Year 2026 release of these programs, effective October 2025, will be compiled with Java 17 and only the Java 17, 64-bit COBOL calling module will be delivered. Providers and their software vendors should begin planning this year to ensure they are prepared for this conversion next fall.

Questions about the Java 17 conversion can be sent at any time to the resource mailbox GrouperBetaTesting@cms.hhs.gov.

Topic # 11 – Administration of emapalumab-lzsg

Issue: There are no unique ICD-10-PCS codes to describe the administration of emapalumab-lzsg. An April 1, 2025 implementation date is being requested.

New Technology Application? Yes. The requestor intends to submit a New Technology Add-on Payment (NTAP) application for FY 2026 consideration.

Food & Drug Administration (FDA) Approval? Yes. GAMIFANT™ (emapalumab-lzsg) was granted FDA approval on November 20, 2018, for the treatment of hemophagocytic lymphohistiocytosis (HLH) with primary HLH refractory, recurrent, or progressive disease and intolerance with conventional HLH therapy in adult and pediatric patients. The requestor intends to submit a Supplemental Biologics License Application (sBLA) in the second half of 2024, with a new indication of treatment in adult and pediatric patients with known or suspected secondary hemophagocytic lymphohistiocytosis (sHLH)/macrophage activation syndrome (MAS) in known or suspected Still's disease (including systemic juvenile idiopathic arthritis [sJIA] and adult-onset Still's disease [AOSD]) with an inadequate response or intolerance to steroids, or with recurrent MAS.

Background: HLH is a rare, frequently fatal, hyperinflammatory syndrome characterized by pathologic immune dysregulation, resulting in overproduction of proinflammatory cytokines such as IFNγ. MAS, a subtype of sHLH, occurs in the context of rheumatic disease and occurs most frequently as a life-threatening complication of Still's disease (i.e., sJIA and AOSD, both rare, autoinflammatory disorders). According to the requestor, the prevalence of sJIA is expected to be ≤8.6 per 100,000 children and the prevalence of AOSD, the adult form of sJIA, is expected to range between 0.73 to 6.77 per 100,000 adults. Additionally, the occurrence of MAS secondary to Still's disease has been reported to range between 5.0-19.5% of patients with AOSD and to be approximately 10% of patients with sJIA. MAS secondary to auto-immune diseases is generally accepted as a rare disease that affects less than 200,000 people in the United States (U.S.). Life-threatening symptoms of MAS include fever, splenomegaly, cytopenias and multiple organ failure.

Per the requestor, the diagnosis of MAS is often delayed due to the lack of awareness of the characteristic signs and complex pattern of presenting features overlap with other hyperinflammatory conditions. There are no individual laboratory or clinical findings that are unique to sHLH/MAS in Still's disease and no single set of validated criteria for diagnosis. Currently, there are no individual laboratory or clinical findings that are unique to sHLH/MAS in Still's disease and no single set of validated criteria for diagnosis. There are no FDA-approved treatments for MAS in Still's disease; and common options for initial therapy (primarily systemic glucocorticoids) are nonspecific and do not address the hyperinflammation caused by the overexpression of interferon gamma (IFNγ); recommended use is not based on robust clinical evidence. Furthermore, glucocorticoids have a low rate of response and are not recommended for long-term use due to their side effects. Given the life-threatening symptoms of MAS in Still's disease, treatments are more likely to take place in the inpatient setting, including elevated intensive care unit admission, and overall lengthy hospital stays. Affected patients are more likely to experience multiple relapses and recurrence of MAS episodes.

According to the requestor, emapalumab-lzsg can address an unmet treatment need for adult and pediatric patients with known or suspected sHLH/MAS in known or suspected Still's disease (including sJIA and AOSD) with an inadequate response or intolerance to steroids, or with recurrent MAS.

Mechanism of Action
GAMIFANT™ (emapalumab-lzsg) is a fully human IgG1 anti-IFNγ monoclonal antibody that binds free and receptor bound IFNγ, neutralizing its biological activity. Overproduction of IFNγ is present and pathogenic in animal models of MAS. In sJIA/AOSD, high IFNγ activity demonstrated by high serum levels of C-X-C motif chemokine ligand 9 (CXCL9), a chemokine selectively induced by IFNγ, is associated with MAS onset and severity.[1] The role of IFNγ in hyperinflammation can be summarized as the following: (1) patients with MAS have an increased proportion of circulating IFNγ-producing activated T cells, (2) diagnosed patients have increased serum levels of IFNγ-induced products that correlate with disease activity, and (3) the excess of cytokines leads to the signs and symptoms of MAS and adversely affects multiple organs. Overactivation of macrophages and T cells can lead to self-perpetuating, overexpression of multiple proinflammatory cytokines. Thus, T cells stimulate macrophages by releasing IFNγ and macrophages stimulate T cells with IL-18 and IL-12. Per the requestor, results of the completed Phase 2 study demonstrated that IFNγ is an important driver of MAS secondary to sJIA/AOSD and that its neutralization with emapalumab-lzsg leads to remission of MAS in patients who failed high-dose glucocorticoids.[1]

Inpatient Administration of emapalumab-lzsg
For the indication of primary HLH, the recommended starting dose for emapalumab-lzsg is 1mg/kg administered via an intravenous infusion utilizing an intravenous line containing a sterile, non-pyrogenic, low-protein binding 0.2-micron inline filter, over 1 hour twice per week (every three to four days). For patients diagnosed with known or suspected sHLH/MAS in Still's disease, the recommended starting dose in the completed Phase 2 study was 6mg/kg, followed by 3mg/kg every 3 days for 5 doses, then 3mg/kg twice per week. Based on clinical response, the dose can be increased, or intervals can be shortened to daily infusions. In the completed Phase 2 study, the median treatment duration was 27 days (range, 7-39), with the number of infusions ranging from 3 to 17 per patient. GAMIFANT™ (emapalumab-lzsg) is supplied as a solution in single-dose vials of 10 mg/2 mL, 50 mg/2 mL and 100 mg/2 mL; it must be stored in a refrigerator at 2ºC to 8ºC (36ºF to 46ºF) in the original carton to protect from light.

Per the requestor, adverse events frequently associated with the administration of emapalumab-lzsg were infections and asymptomatic positive viral tests. All infectious events were of viral origin and were mild or moderate in intensity; no bacterial or opportunistic infections were reported. One cytomegalovirus (CMV) reactivation was reported as serious. In total, there were five CMV events (three reactivations, one infection and one positive test with no symptoms). All viral events resolved spontaneously or with standard treatment. Two mild infusion-related reactions (pruritic rash) occurred during a total of 128 infusions. Additionally, there was an

[1] De Benedetti, F., Grom, A. A., Brogan, P. A., Bracaglia, C., Pardeo, M., Marucci, G., Eleftheriou, D., Papadopoulou, C., Schulert, G. S., Quartier, P., Antón, J., Laveille, C., Frederiksen, R., Asnaghi, V., Ballabio, M., Jacqmin, P., & de Min, C. (2023). Efficacy and safety of emapalumab in macrophage activation syndrome. *Annals of the rheumatic diseases*, *82*(6), 857–865. https://doi.org/10.1136/ard-2022-223739

incidence of cardiopulmonary failure and neutropenia, not directly related to use of GAMIFANT™ (emapalumab-lzsg). No instances of death were reported during the trial or in the long-term follow-up.

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of emapalumab-lzsg. Facilities can report the intravenous administration of emapalumab-lzsg using one of the following codes:

3E033GR	Introduction of other therapeutic monoclonal antibody into peripheral vein, percutaneous approach
3E043GR	Introduction of other therapeutic monoclonal antibody into central vein, percutaneous approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the intravenous administration of emapalumab-lzsg. Continue coding as listed in current coding.

Option 2. Create new codes in section X, New Technology, to identify the intravenous administration of emapalumab-lzsg.

Section	**X** New Technology		
Body System	**W** Anatomical Regions		
Operation	**0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products		
Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD D** Emapalumab-lzsg Anti-IFNγ Monoclonal Antibody	**A** New Technology Group 10

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using current codes as listed in current coding.

Topic # 12 – Administration of tarlatamab-dlle

Issue: There are no unique ICD-10-PCS codes to describe the administration of tarlatamab-dlle. An April 1, 2025 implementation date is being requested.

New Technology Application? Yes. The requestor intends to submit a New Technology Add-on Payment (NTAP) application for FY 2026 consideration.

Food & Drug Administration (FDA) Approval? Yes. The requestor was granted accelerated Biologics License Application (BLA) approval for tarlatamab-dlle by the FDA on May 16, 2024. IMDELLTRA™ (tarlatamab-dlle) is indicated for the treatment of adult patients with extensive stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy. Breakthrough Therapy Designation was granted in October 2023 and priority review was granted on December 12, 2023. The indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). The FDA set a Prescription Drug User Fee Act (PDUFA) date of June 12, 2024.

Background: SCLC is one of the most aggressive and devastating solid tumors, with a median survival of approximately 12 months following initial therapy and a 7% five-year relative survival rate when all stages are combined.[1,2,3,4,5] In 2024, it is estimated that there will be approximately 30,000 to 35,000 new cases of SCLC in the United States.[6] Despite initial high response rates to platinum-based first-line chemotherapy, SCLC patients quickly relapse and require subsequent treatment options.[7] In addition, SCLC has a high rate of molecular alterations and no actionable biomarkers exist currently. Approximately 85% to 96% of SCLC patients have expression of delta-like ligand 3 (DLL3) on the cell surface of SCLC cells, with minimal expression in normal cells.[8,9,10,11]

Mechanism of Action
IMDELLTRA™ (tarlatamab-dlle) is a bispecific DLL3-directed CD3 T-cell engager that binds to DLL3 expressed on the surface of cells, including tumor cells, and CD3 expressed on the surface of T cells. Per the requestor, tarlatamab-dlle causes T-cell activation, release of inflammatory cytokines, and lysis of DLL3-expressing cells.

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[1] Amgen Press Release, "FDA approves IMDELLTRA (tarlatamab-dlle), the first and only t-cell engager therapy for the treatment of extensive-stage small cell lung cancer," (May 16, 2024). Available at: https://wwwext.amgen.com/newsroom/press-releases/2024/05/fda-approvesimdelltra-tarlatamabdlle-the-first-and-only-tcell-engager-therapy-for-thetreatment-of-extensivestage-small-cell-lung-cancer. Accessed May 17, 2024.
[2] Amgen Press Release, "FDA grants priority review to Amgen's Tarlatamab application," (December 13, 2023). Available at: https://wwwext.amgen.com/newsroom/press-releases/2023/12/fda-grantspriority-review-to-amgens-tarlatamab-application-for-advanced-small-cell-lungcancer. Accessed June 7, 2024.
[3] Paz-Ares L, et al. ESMO Open. 2022;7:100408.
[4] American Cancer Society. Lung Cancer Survival Rates. 2023. Available at: https://www.cancer.org/cancer/types/lung-cancer/detection-diagnosisstaging/survival-rates.html. Accessed June 7, 2024.
[5] Liu SV, et al. J Clin Oncol. 2021;39:619-630.
[6] American Cancer Society, "Cancer Facts & Figures 2024," (January 14, 2024). Available at: https://www.cancer.org/content/dam/cancerorg/research/cancer-facts-and-statistics/annual-cancer-facts-andfigures/2024/2024-cancer-facts-and-figures-acs.pdf. Accessed June 7, 2024.
[7] Oronsky B, et al. J Cancer. 2022;13:2945-2953.
[8] Giffin MJ, et al. Clin Cancer Res. 2021;27:1526-1537.
[9] Rojo F, et al. Lung Cancer. 2020;147:237-243.
[10] Paz-Ares L, et al. J Clin Oncol. 2023;41:2893-2903.
[11] Ahn M-J, et al. N Engl J Med. 2023;389:2063-2075.

Inpatient Administration of tarlatamab-dlle
In clinical studies, tarlatamab-dlle has been administered in the inpatient setting; however, the requestor stated its clinical profile supports both hospital inpatient and hospital outpatient administration. The treatment is administered by a qualified healthcare provider in an appropriate healthcare setting, via a 1-hour intravenous (IV) infusion through the central or peripheral vein. Appropriate medical support is recommended to manage severe reactions such as cytokine release syndrome (CRS) and neurologic toxicity including immune effector cell-associated neurotoxicity syndrome (ICANS). According to the prescribing information, tarlatamab-dlle is administered in cycles primarily as a standalone procedure. However, there are doses that will require concomitant medications. Cycle 1 consists of a step-up dosing schedule of 1 mg on Day 1 followed by 10 mg on Days 8 and 15. During cycle 1, patients should be monitored for 22 to 24 hours from the start of the first and second infusions (Day 1 and Day 8) in an appropriate healthcare setting, and for 6 to 8 hours after the third infusion (Day 15). Additionally, patients are recommended to remain within a 1-hour distance of an appropriate healthcare setting for a total of 48 hours from the start of the infusion and be accompanied by a caregiver. An inpatient stay could be necessary due to the minimum recommended monitoring time and administration of concomitant medications before and after infusions.

For cycles 2 to 5 and subsequent infusions, the recommended dosing of tarlatamab-dlle is 10 mg every 2 weeks unless there is disease progression or there are unacceptable levels of toxicity. During cycle 2 patients should be monitored for 6-8 hours after infusions. During cycles 3 and 4, patients should be monitored for 3-4 hours after infusions. For cycle 5 and any subsequent infusions, patients should be monitored for 2 hours after infusions. After the step-up dosing schedule, extended monitoring in a healthcare setting is not required unless the patient experiences grade 2 or higher CRS, ICANS, or neurological toxicity during prior treatments. Patients that experience grade 2 or 3 CRS, neurological toxicity or ICANS should be monitored for 22 to 24 hours following the next dose. If a patient experiences grade 2 or higher CRS, hospitalization is recommended. If a patient experiences grade 3 CRS, neurological toxicity including ICANS, monitoring in the intensive care unit is recommended. For grade 4 CRS, neurological toxicity including ICANS, patients must be managed in the intensive care unit. In the occurrence of severe adverse events, tarlatamab-dlle should be withheld or permanently discontinued.

According to the requestor, 58% of patients who received IMDELLTRA™ (tarlatamab-dlle) in clinical studies experienced serious adverse reactions. Serious adverse reactions in >3% of patients included CRS, pneumonia, pyrexia, and hyponatremia. CRS occurred in 55% of patients and 1.6% of treated patients developed grade 3 or 4 CRS. Recurrent CRS occurred in 24% of patients. Neurologic toxicity including ICANS occurred in 47% of patients and ICANS alone occurred in 9%, respectively. Additionally, the most common (≥20%) adverse reactions were CRS, fatigue, pyrexia, dysgeusia, decreased appetite, musculoskeletal pain, and constipation. The most common (≥2%) grade 3 or 4 laboratory abnormalities were decreased lymphocytes, decreased sodium, increased uric acid, decreased total neutrophils, decreased hemoglobin, increased activated partial thromboplastin time, decreased potassium, increased aspartate aminotransferase, decreased white blood cells, decreased platelets and increased alanine aminotransferase. Permanent discontinuation of tarlatamab-dlle due to an adverse reaction occurred in 7% of patients, with 1.6% of patients permanently discontinuing due to CRS and 1.1% of patients discontinuing due to tumor lysis syndrome. A *boxed warning* for CRS and neurological toxicities with ICANS is included in the prescribing information for IMDELLTRA™ (tarlatamab-dlle).

Current Coding: There are no unique ICD-10-PCS codes to describe the administration of tarlatamab-dlle. Facilities can report the intravenous administration of tarlatamab-dlle using one of the following codes:

3E03305 Introduction of other antineoplastic into peripheral vein, percutaneous approach
3E04305 Introduction of other antineoplastic into central vein, percutaneous approach

Coding Options

Option 1. Do not create new ICD-10-PCS codes for the intravenous administration of tarlatamab-dlle. Continue coding as listed in current coding.

Option 2. Create new codes in section X, New Technology, to identify the intravenous administration of tarlatamab-dlle.

Section	**X** New Technology
Body System	**W** Anatomical Regions
Operation	**0** Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products

Body Part	*Approach*	*Device / Substance / Technology*	*Qualifier*
3 Peripheral Vein **4** Central Vein	**3** Percutaneous	**ADD C** Tarlatamab-dlle Antineoplastic	**A** New Technology Group 10

CMS Recommendation: Option 2, as described above.

Interim Coding Advice: Continue using codes as described in current coding.